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Stroup et al.

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(54) MEDICAL INFUSION DEVICE

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(73) Assignee: **Alliance Vascular Devices, LLC**, Santee, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(65) **Prior Publication Data**

US 2015/0231331 A1 Aug. 20, 2015

Related U.S. Application Data

(63) Continuation of application No. 14/541,796, filed on Nov. 14, 2014, now Pat. No. 9,050,130, which is a continuation of application No. 14/488,982, filed on Sep. 17, 2014, now abandoned.

(60) Provisional application No. 61/879,550, filed on Sep. 18, 2013.

(51) **Int. Cl.**
A61M 5/158 (2006.01)
A61M 39/02 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61M 5/158*** (2013.01); ***A61M 5/1626*** (2013.01); ***A61M 39/02*** (2013.01); ***A61M 39/04*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61M 5/1408; A61M 5/1582; A61M 5/3232; A61M 5/326; A61M 5/3271; A61M 5/3243; A61M 2005/1585; A61M 2005/325; A61M 2005/14252; A61M 2005/14513; A61M 2005/3226; A61M 2005/1403; A61M 2205/14256; A61M 2005/14284; A61M 2005/3242; A61M 2005/3258; A61M 2005/1581; A61M 2039/1072; F04B 33/00; F04B 45/033; F04B 45/0333
See application file for complete search history.

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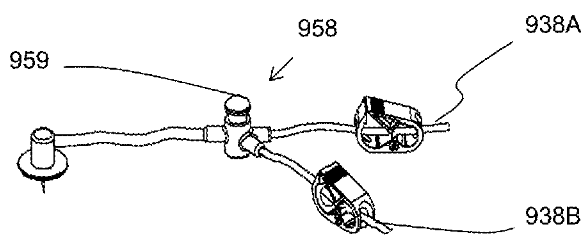
(57) **ABSTRACT**

A medical infusion device including a chamber characterized by an upper body joined to a lower body by a reversibly collapsible sidewall, affixed to the upper body is a downward extending needle, wherein the upper body has two channels, the first channel fluidly coupled to the needle and the second channel fluidly coupled to the interior of the chamber. The chamber has a collapsed state and an expanded state where chamber is configured to transition from the collapsed state to the expanded state by introducing fluid into the interior of the chamber.

21 Claims, 22 Drawing Sheets



(51) **Int. Cl.**

A61M 39/04	(2006.01)
A61M 39/22	(2006.01)
A61M 5/162	(2006.01)

(52) **U.S. Cl.**

CPC ***A61M 39/22*** (2013.01); *A61M 2005/1581* (2013.01); *A61M 2005/1585* (2013.01); *A61M 2039/0205* (2013.01); *A61M 2205/7536* (2013.01)

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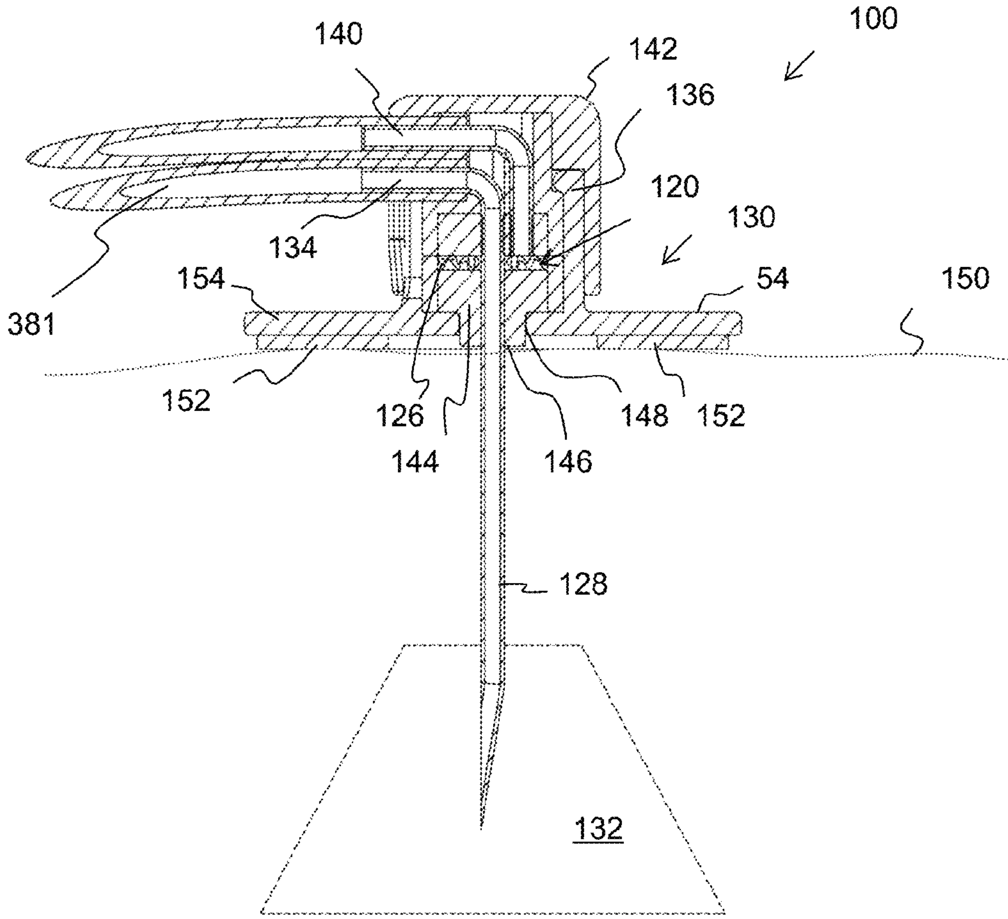
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FIG. 1A

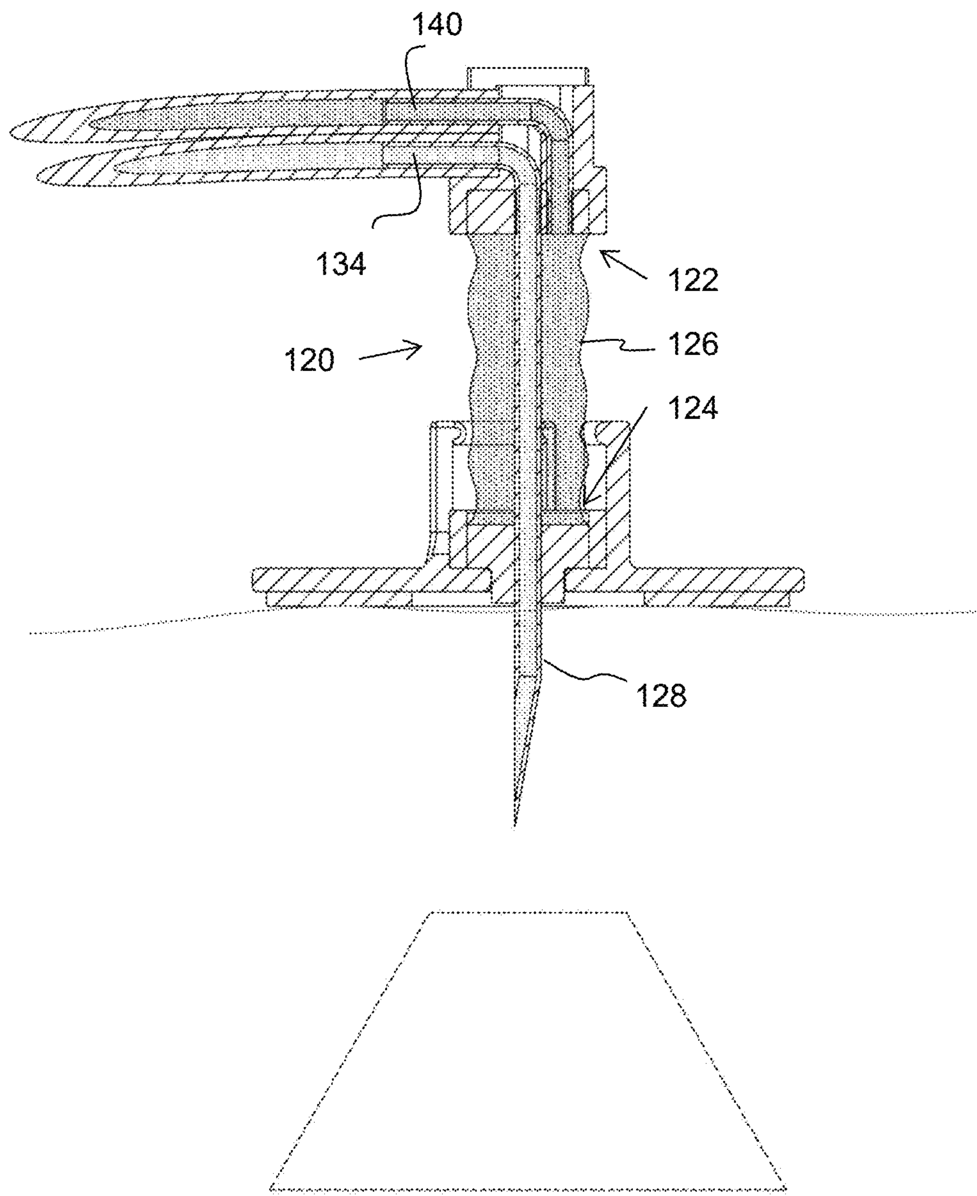


FIG. 1B

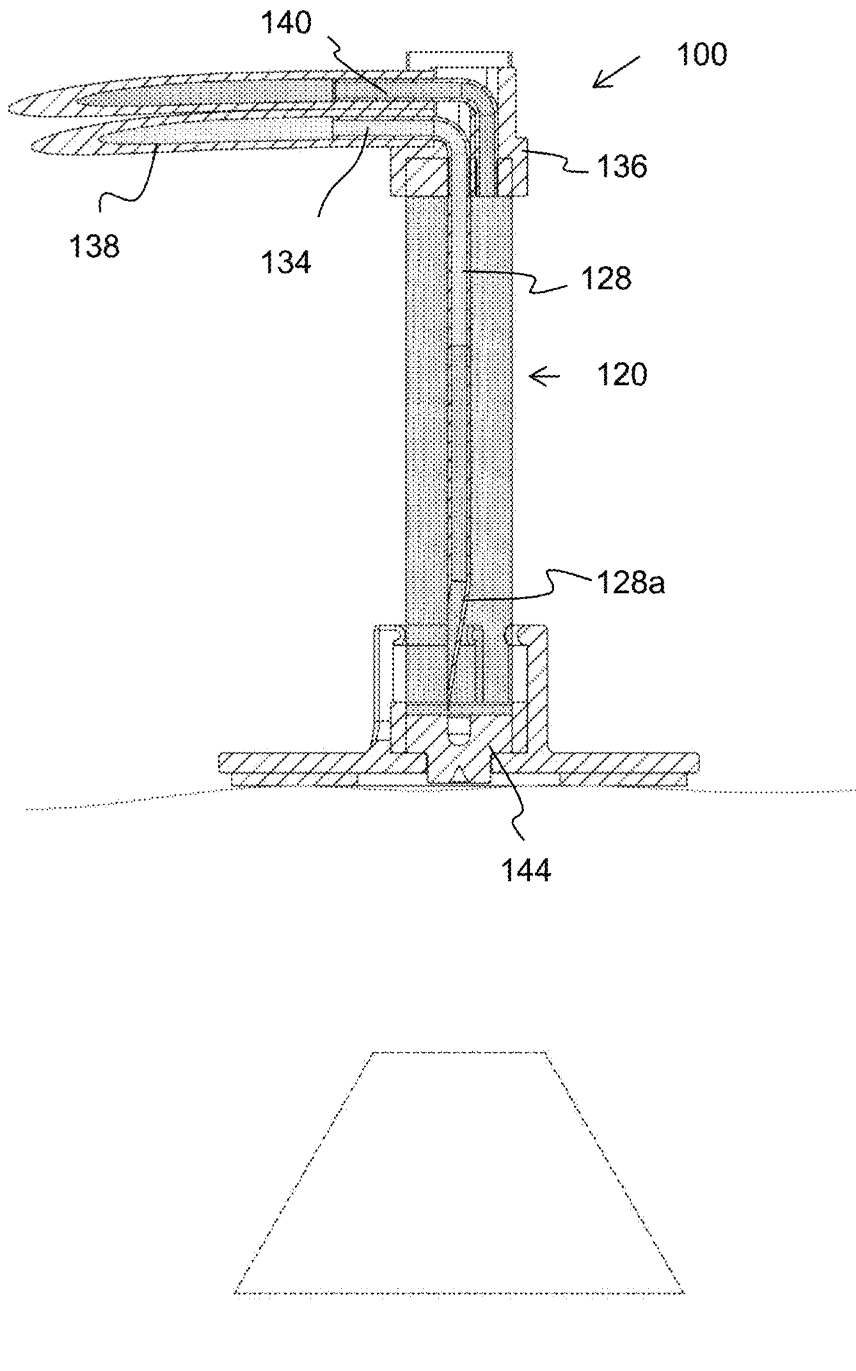


FIG. 1C

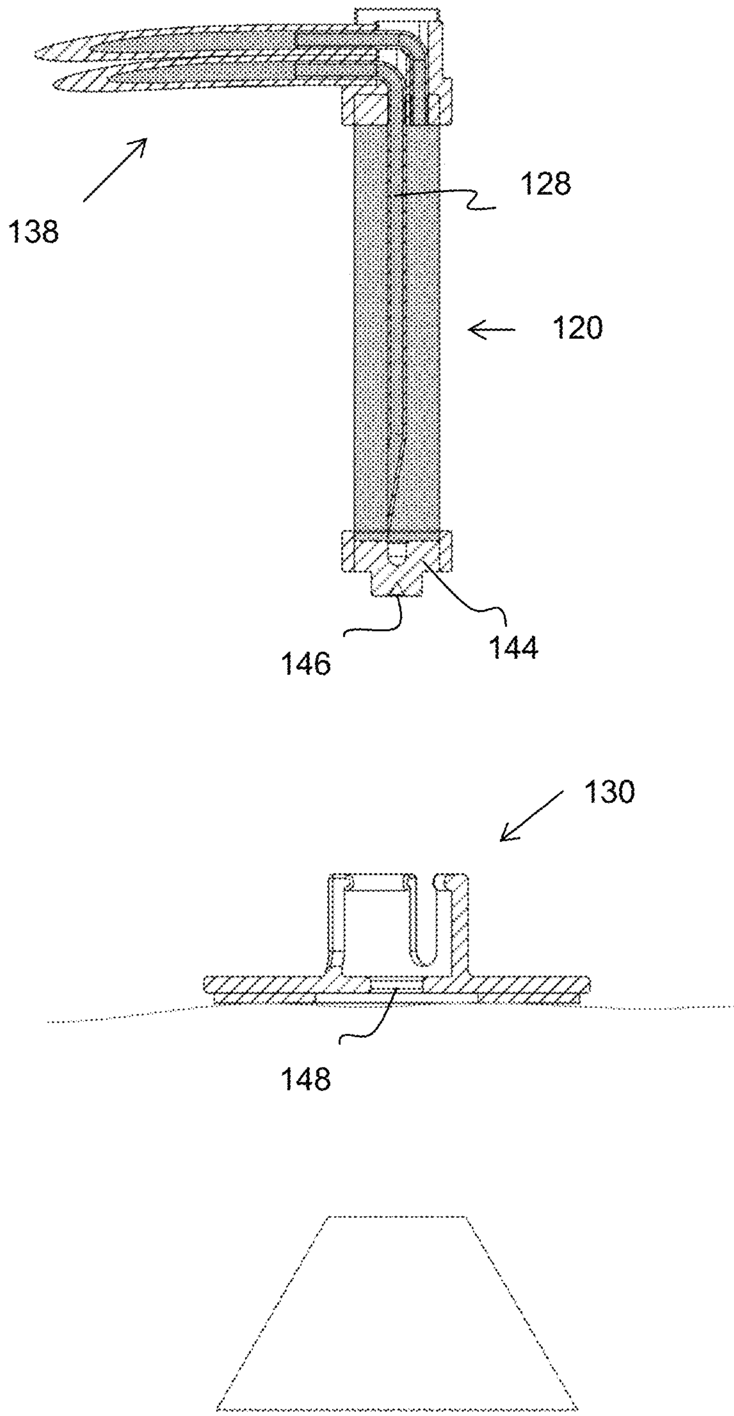


FIG. 1D

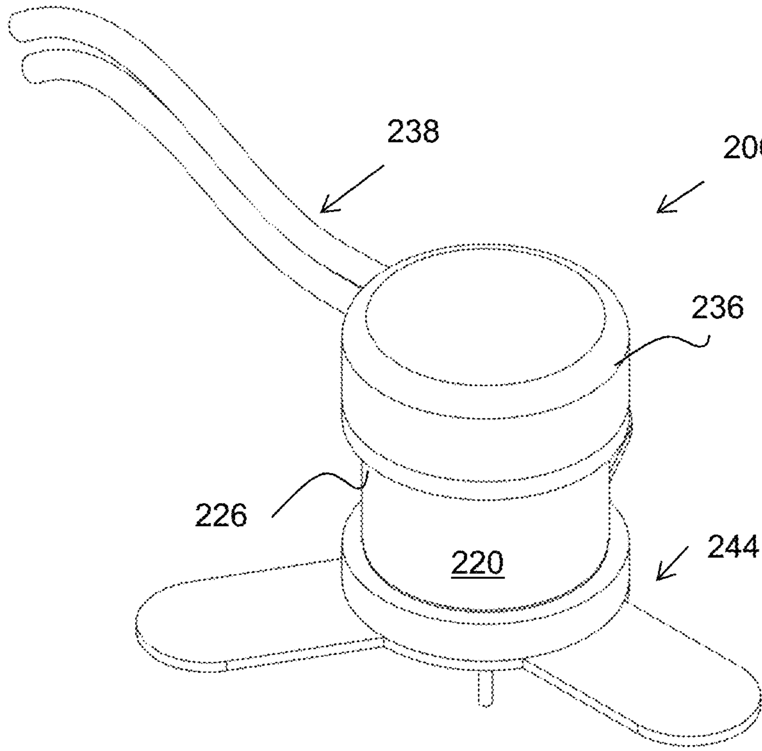


FIG. 2A

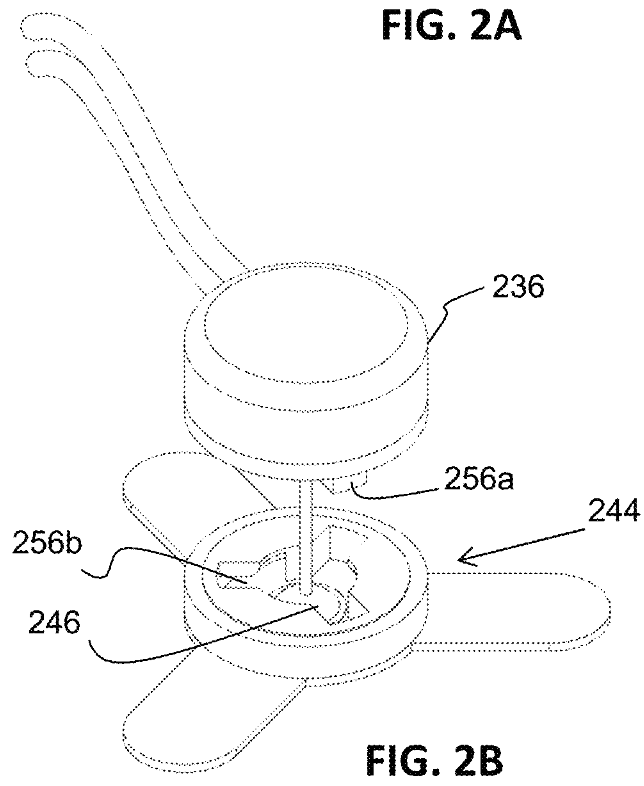
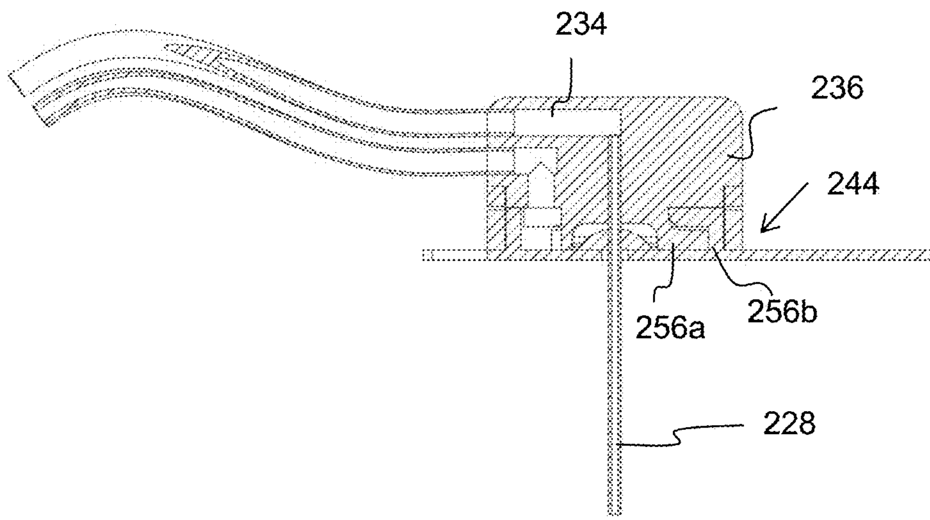


FIG. 2B



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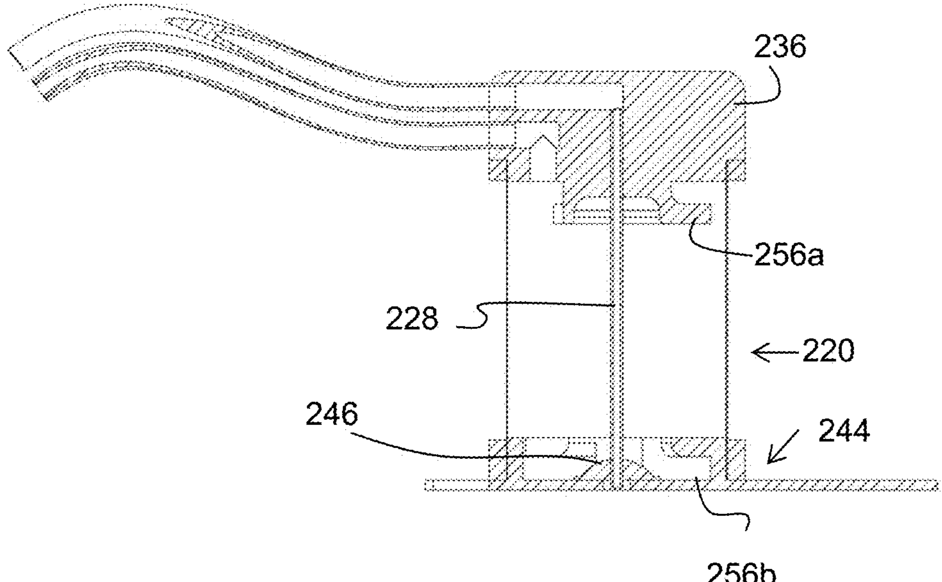

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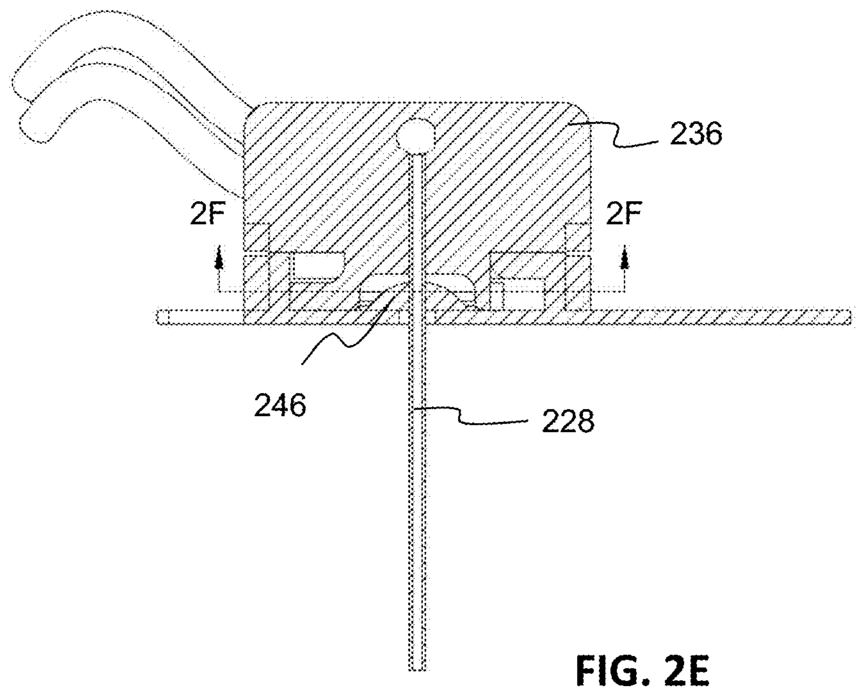


FIG. 2E

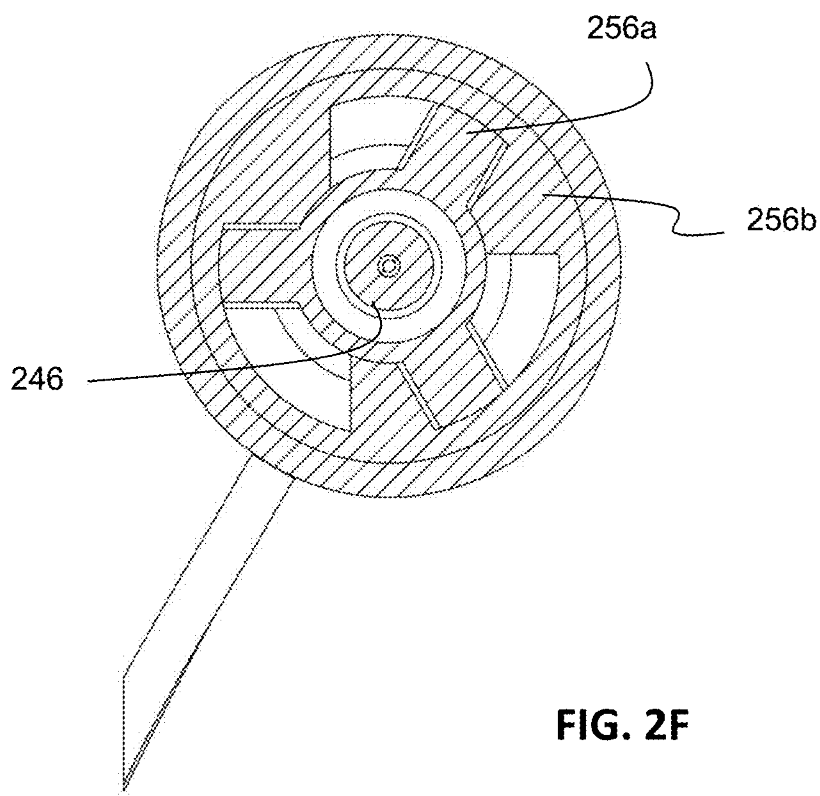


FIG. 2F

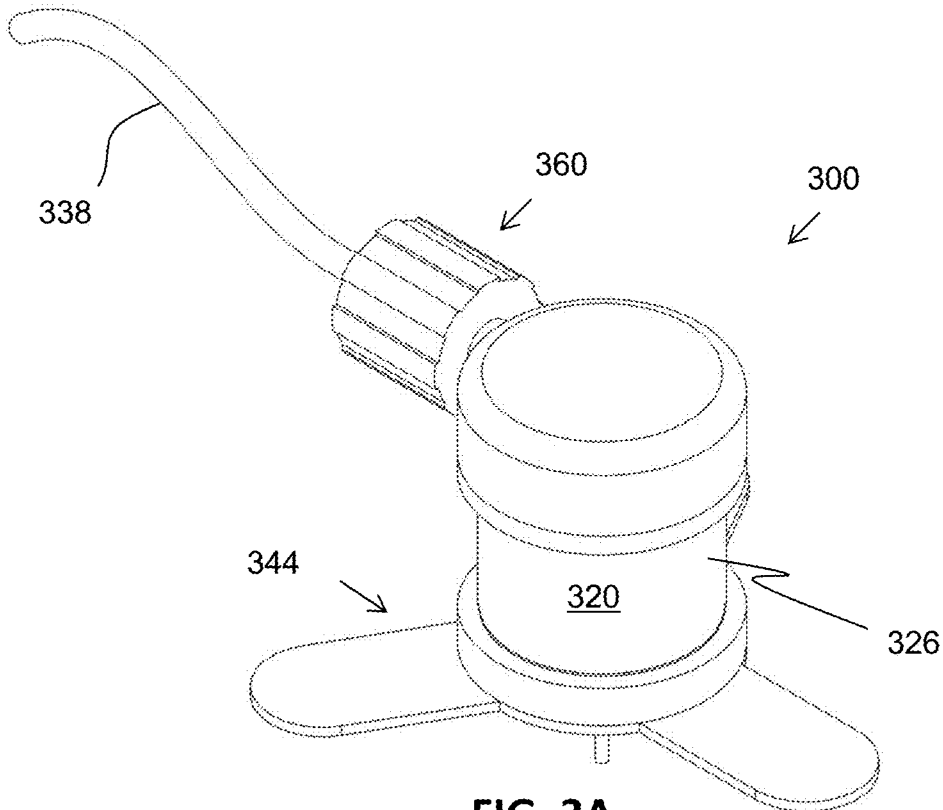


FIG. 3A

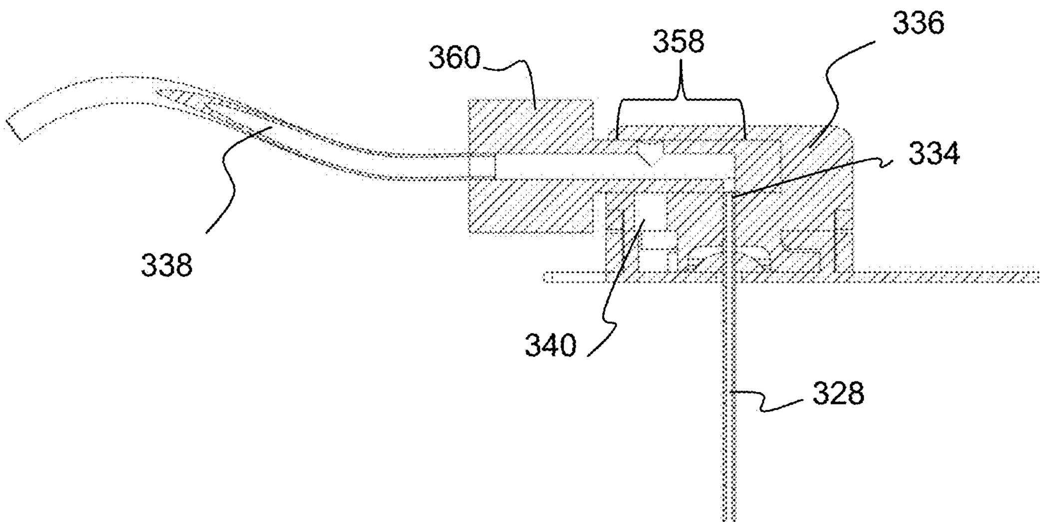
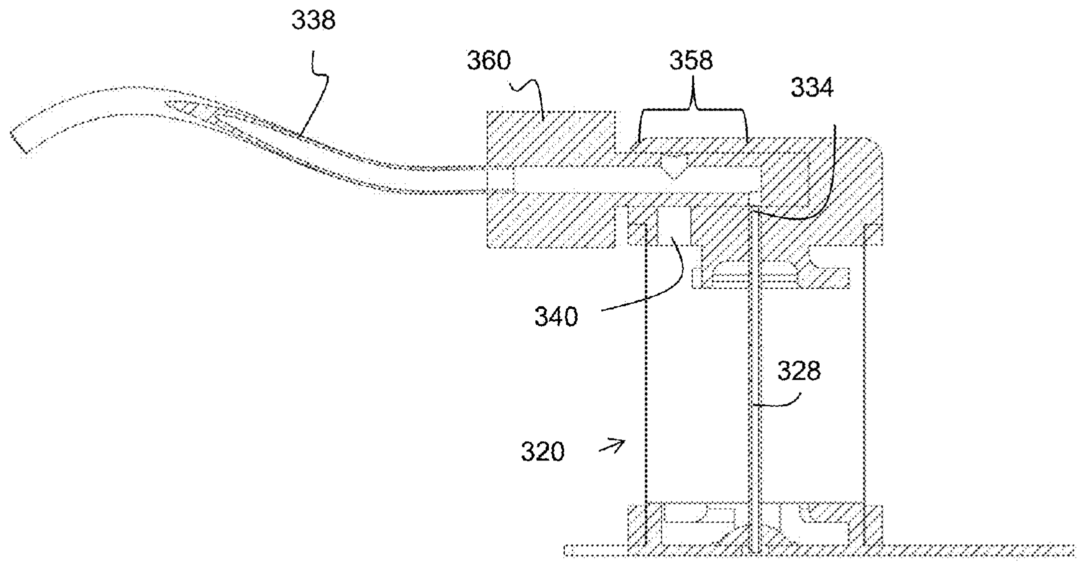


FIG. 3B



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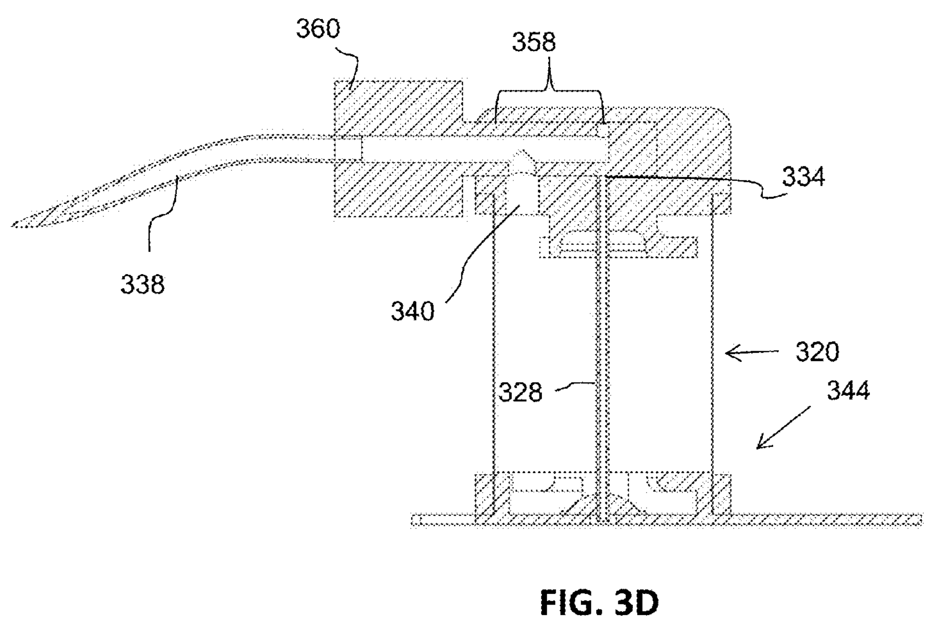

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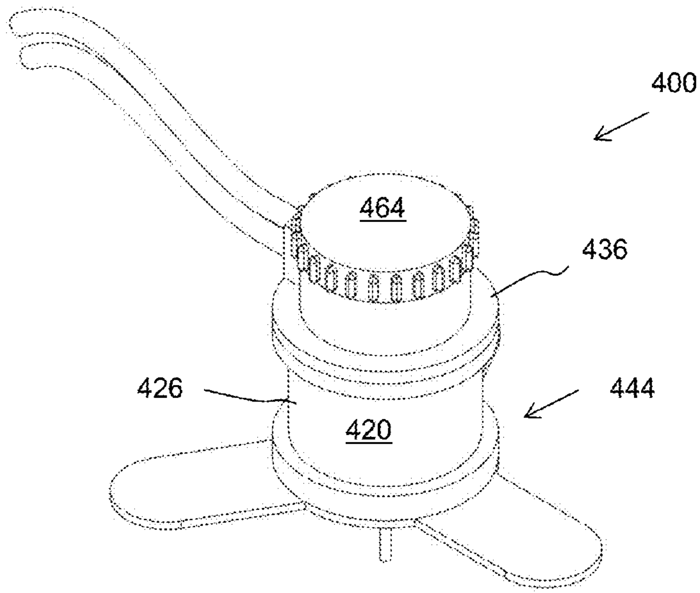
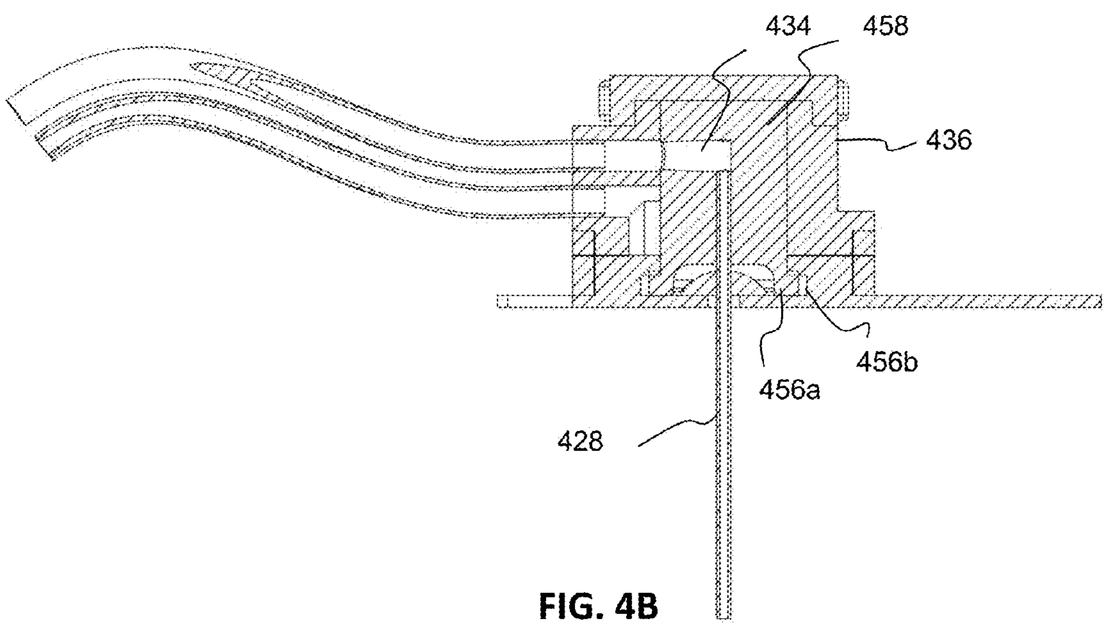


FIG. 4A



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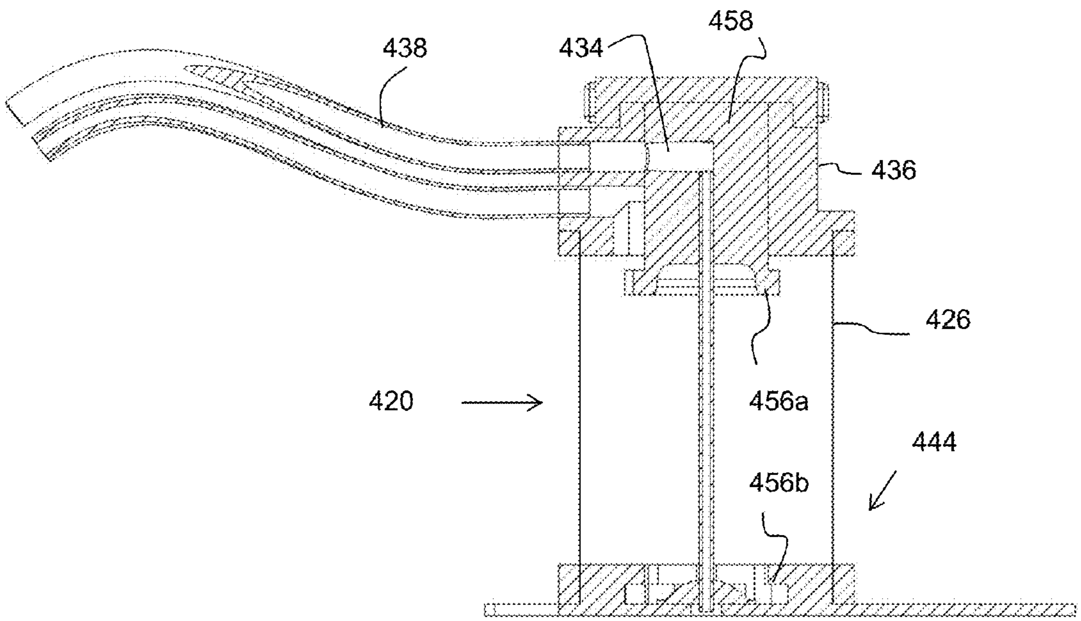
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FIG. 4C

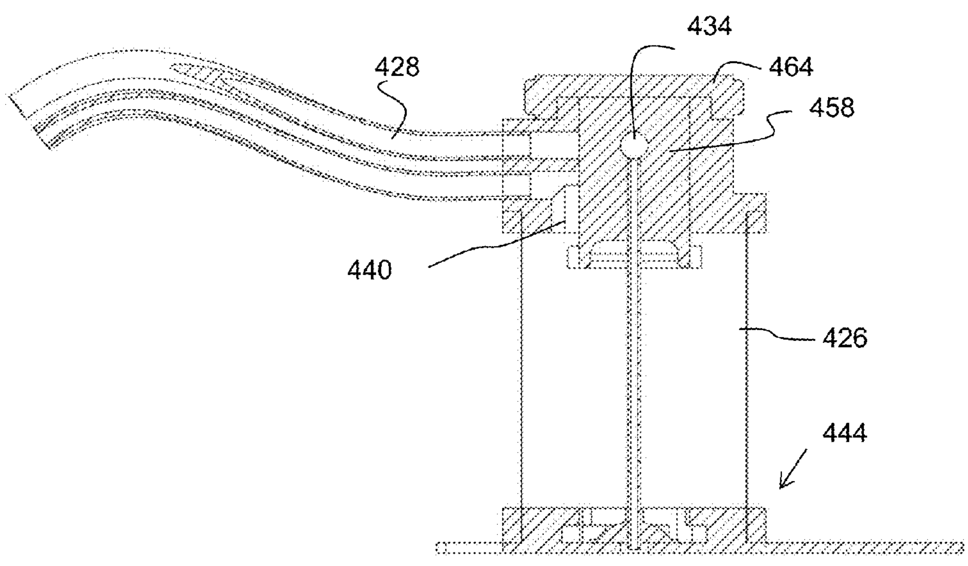
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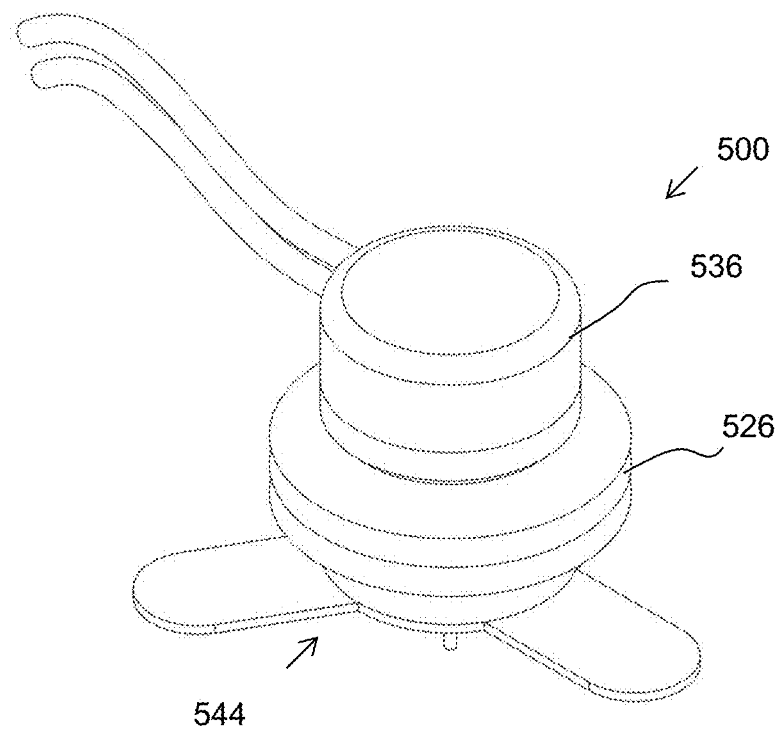
FIG. 4D



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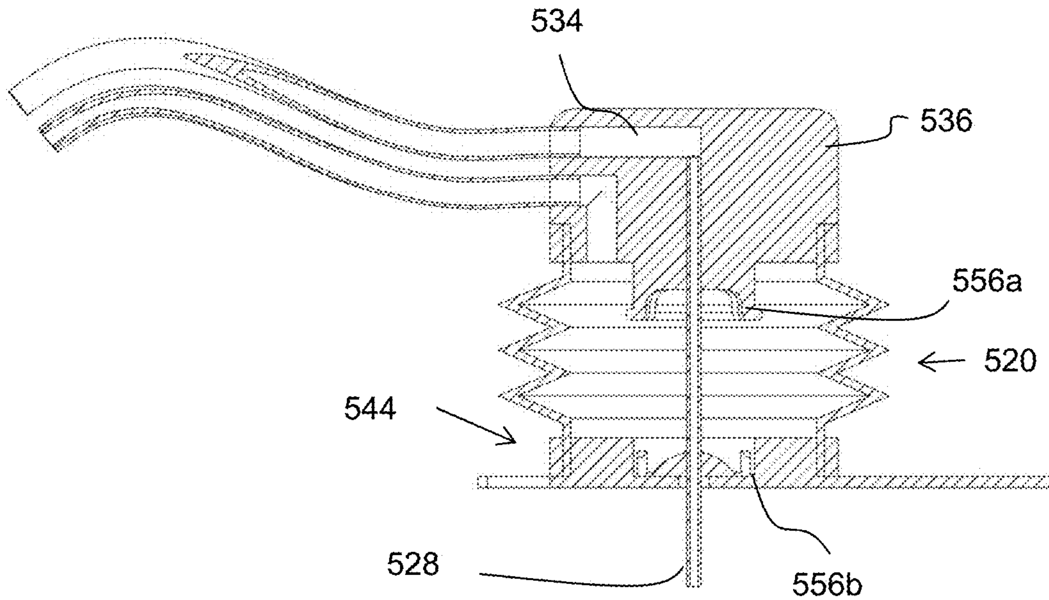

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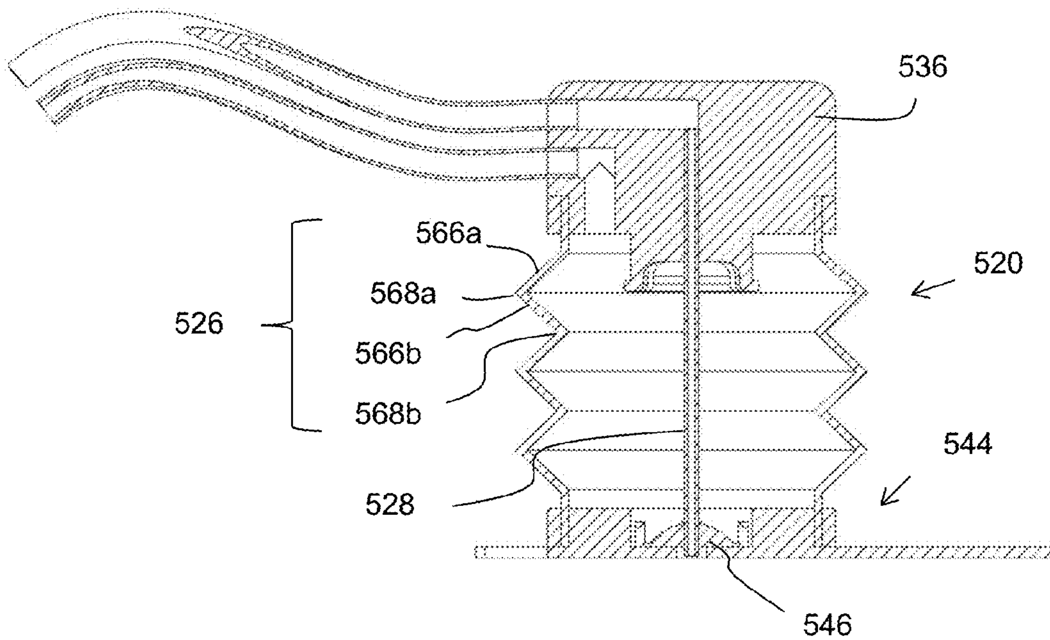
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FIG. 5C

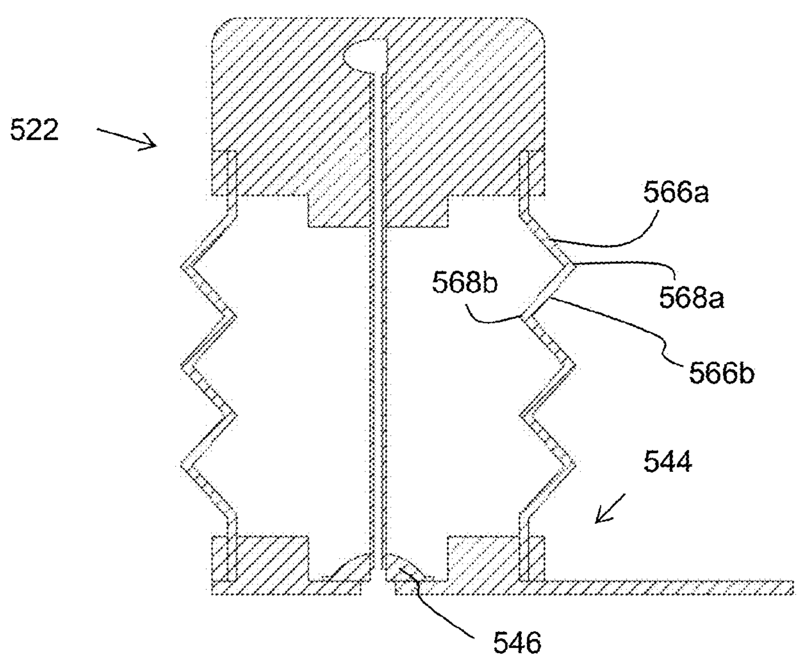
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FIG. 5D

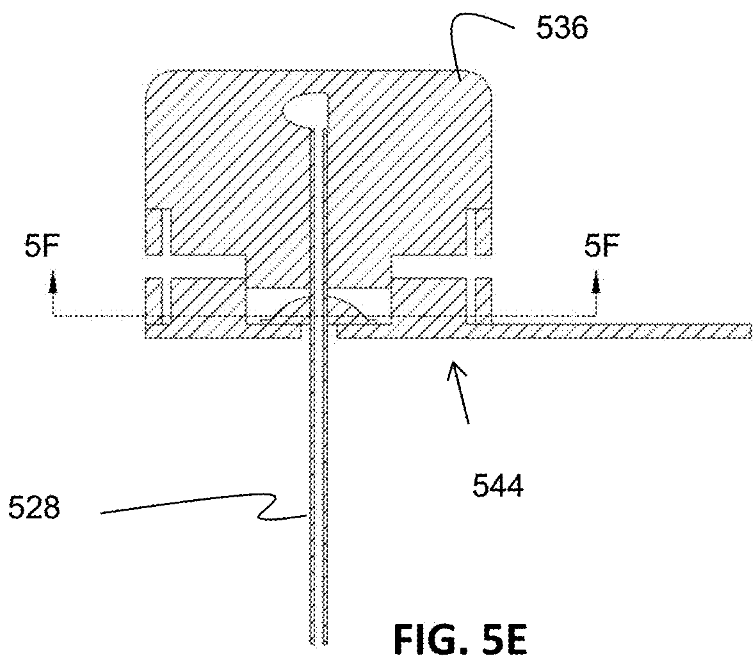


FIG. 5E

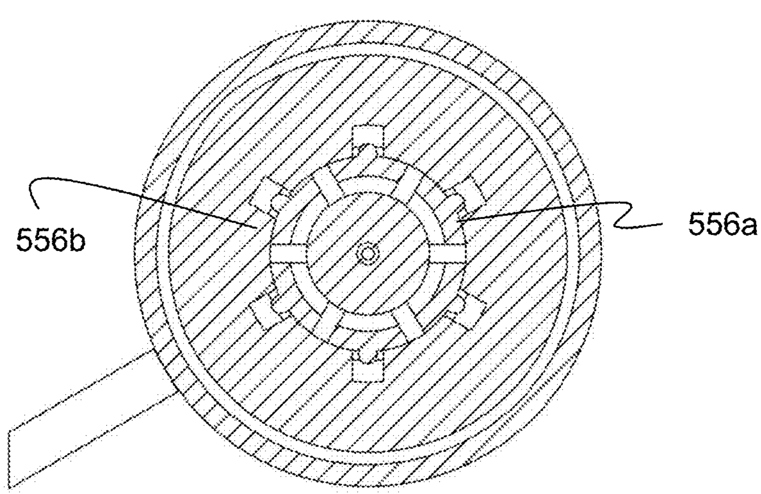


FIG. 5F

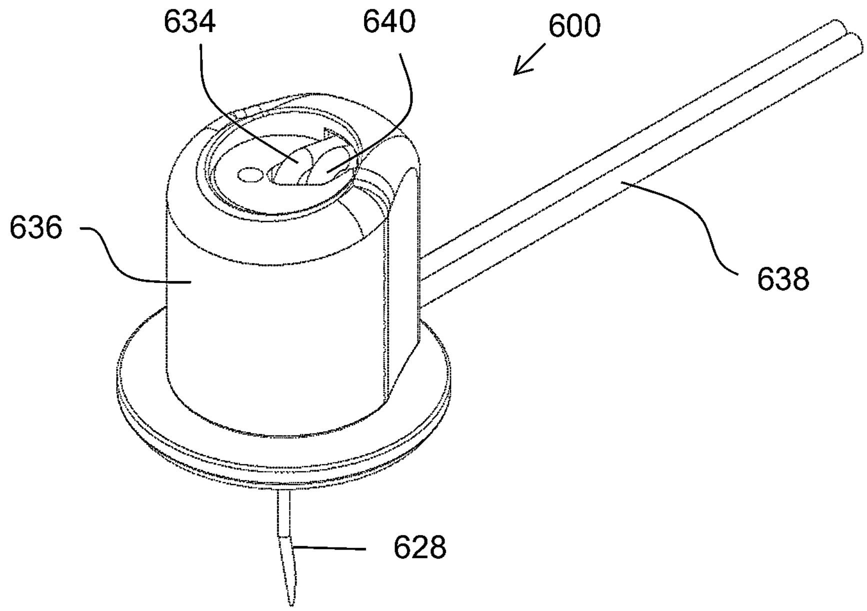


FIG. 6A

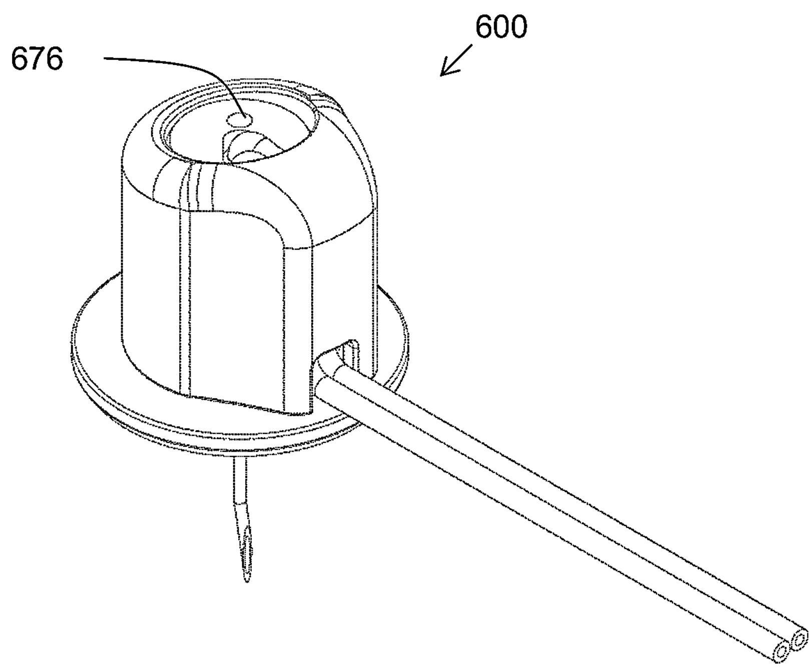


FIG. 6B

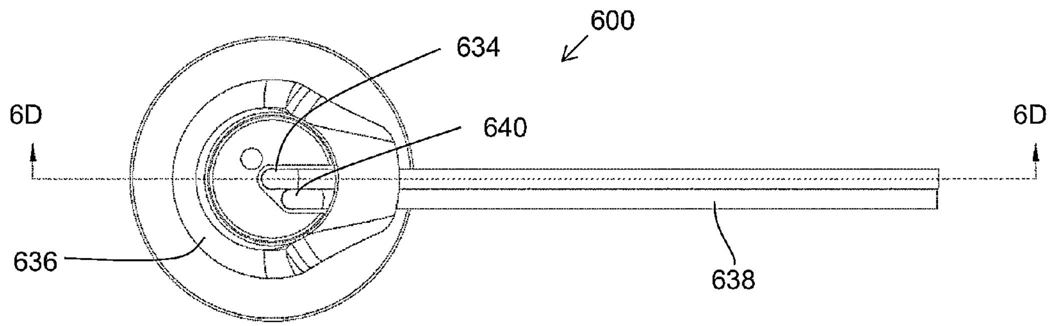


FIG. 6C

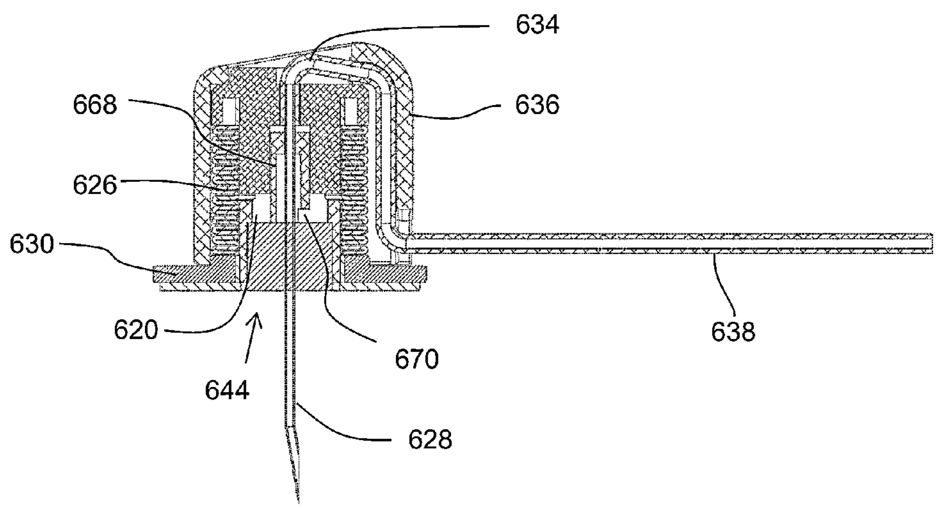


FIG. 6D

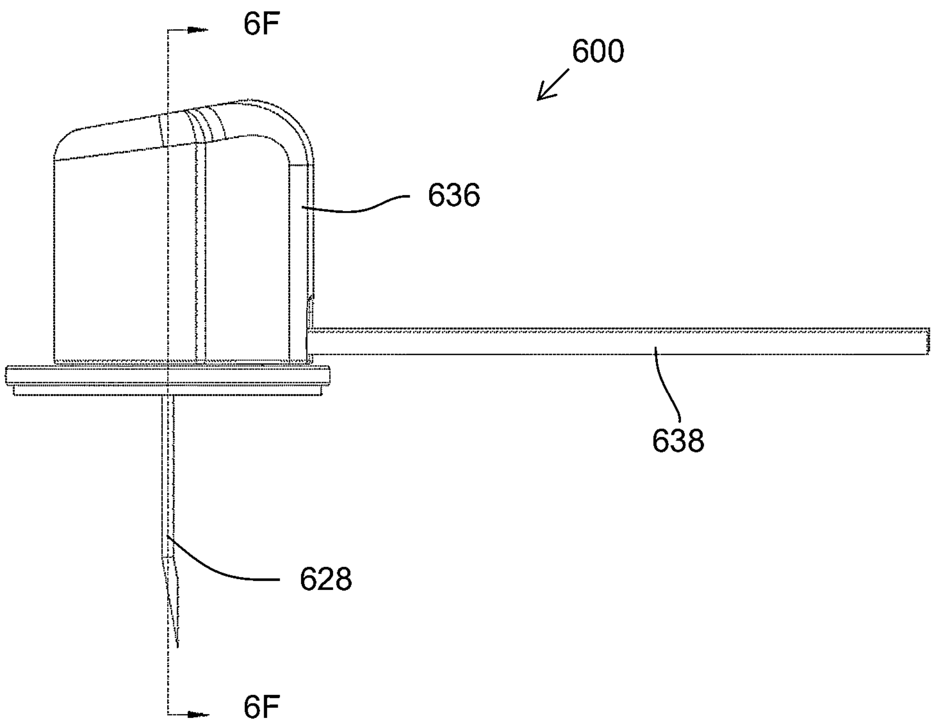


FIG. 6E

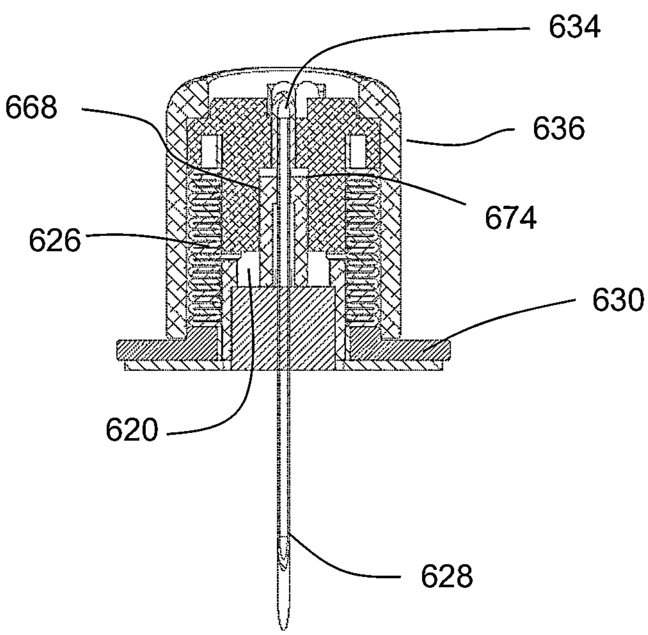
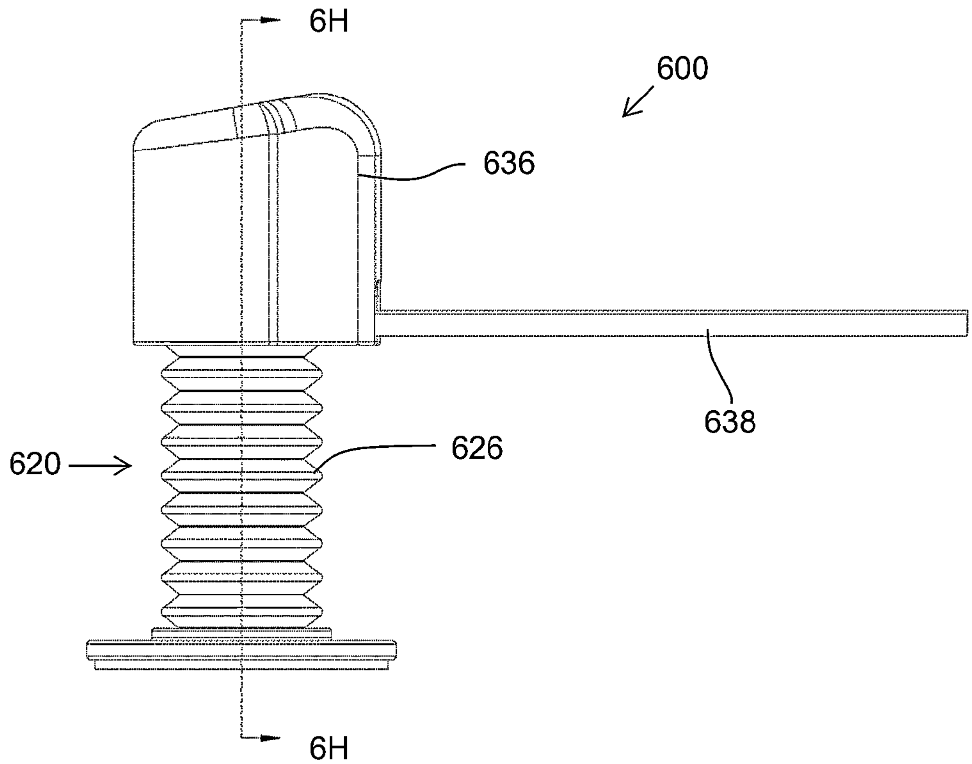


FIG. 6F



6H
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6H

FIG. 6G

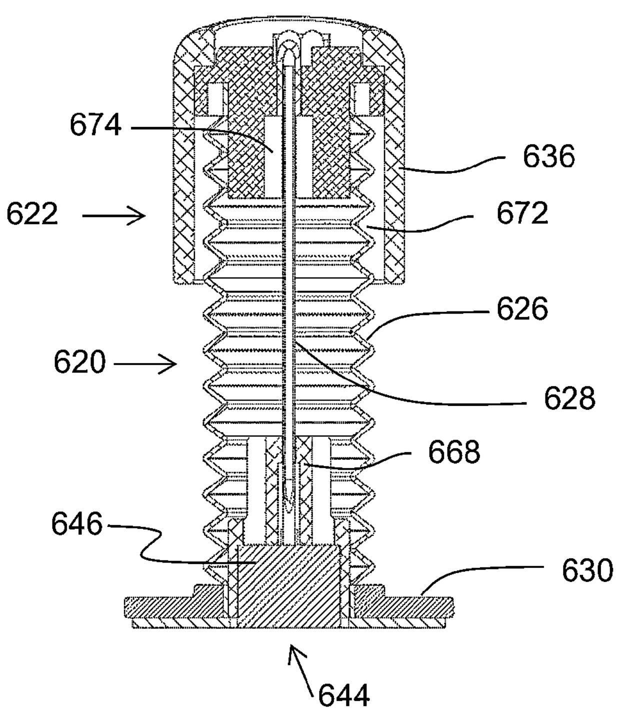

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FIG. 6H

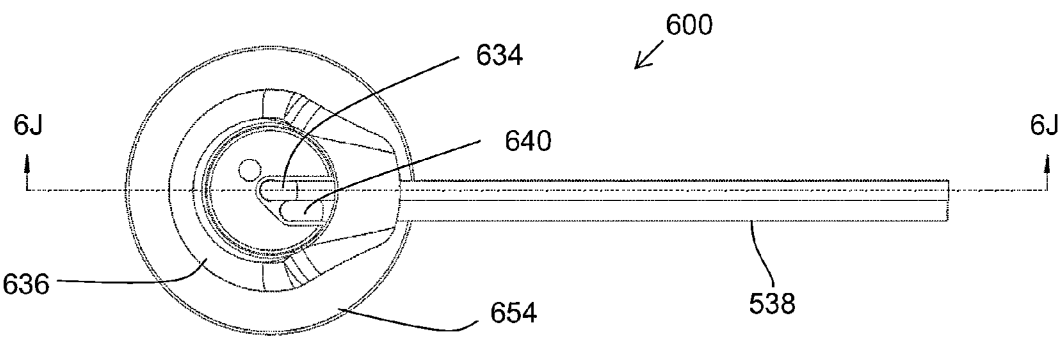
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FIG. 6I

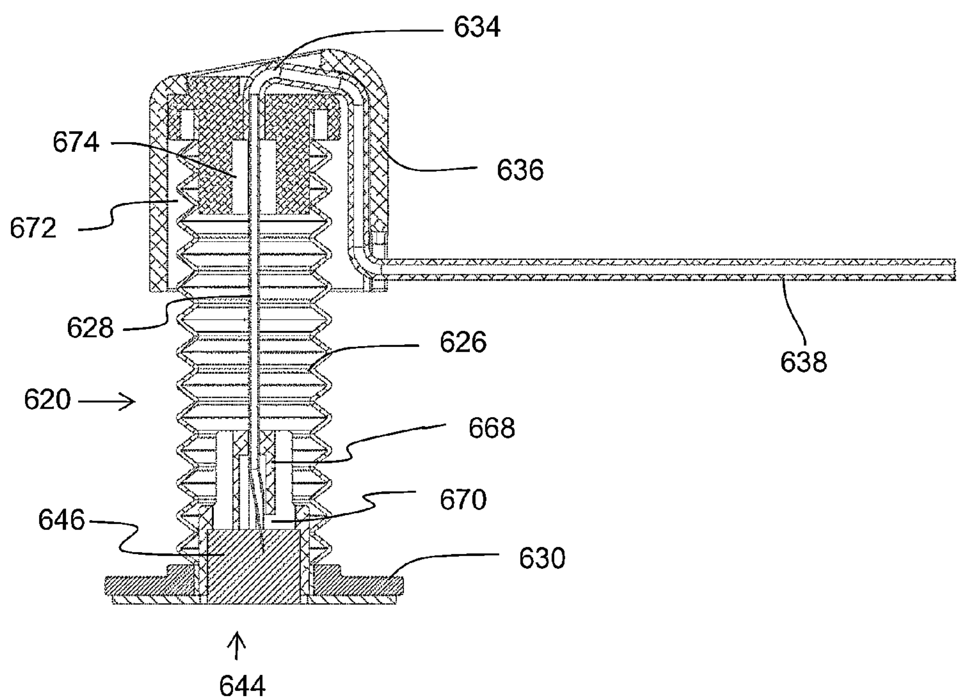
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FIG.6J

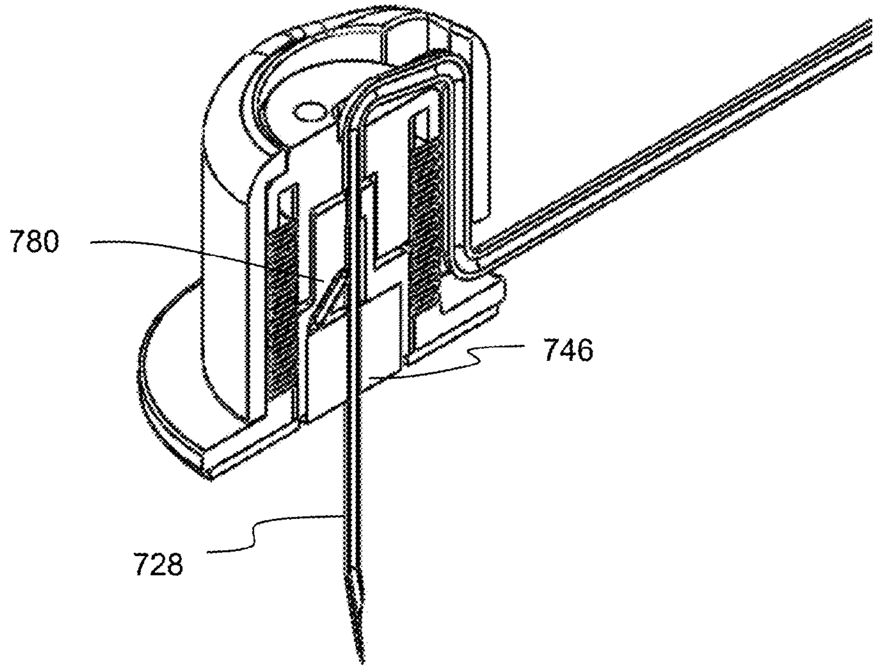

FIG.7A

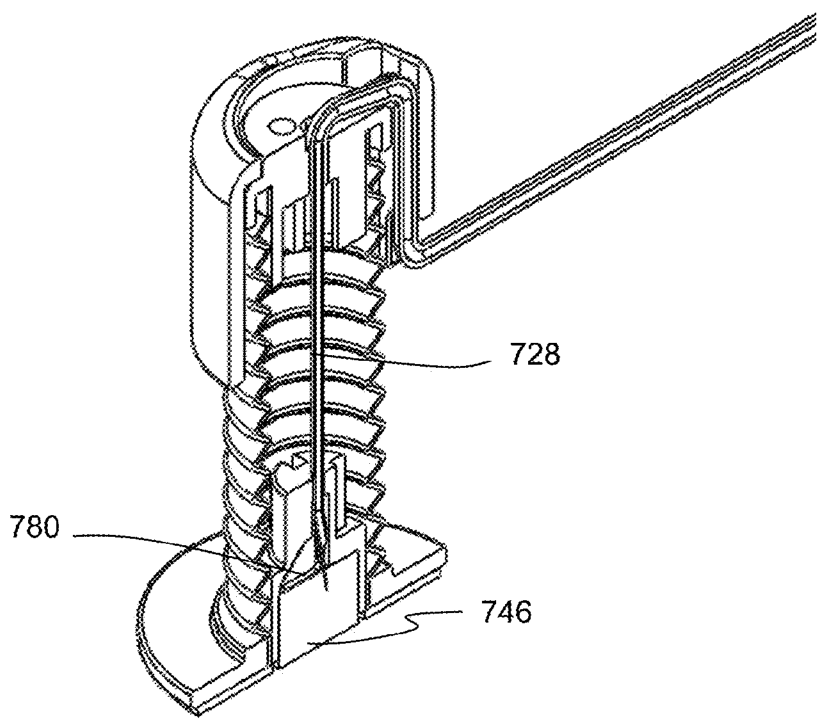

FIG.7B

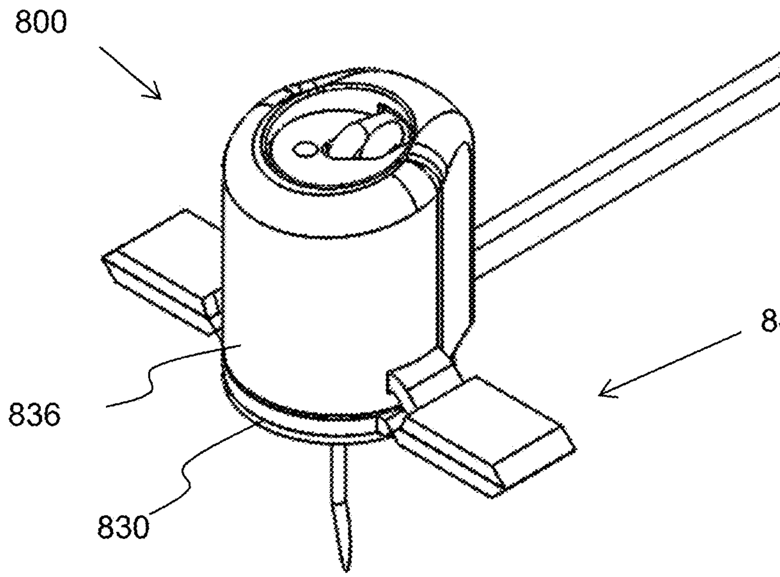

FIG.8A

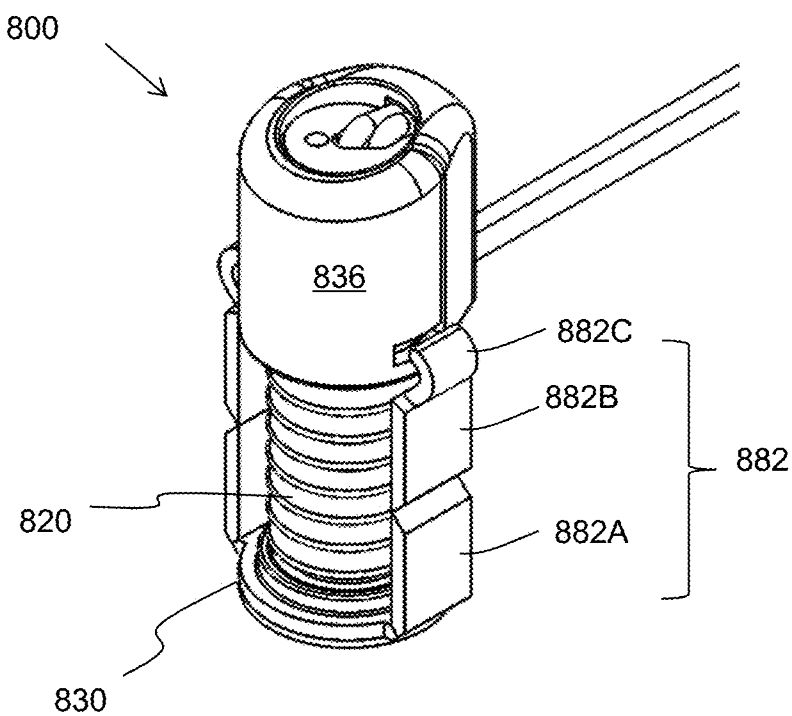

FIG.8B

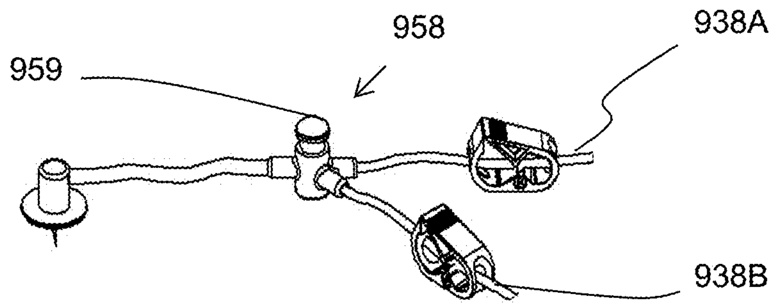

FIG.9A

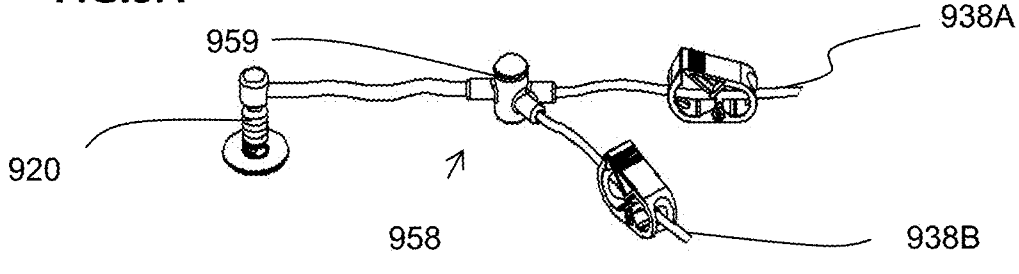

FIG.9B

MEDICAL INFUSION DEVICE

CROSS REFERENCE TO RELATED APPLICATIONS

This is a continuation of U.S. patent application Ser. No. 14/541,796, filed Nov. 14, 2014, now U.S. Pat. No. 9,050,130, which is itself a continuation of U.S. patent application Ser. No. 14/488,982, filed Sep. 17, 2014, now abandoned, which itself claims priority to U.S. provisional patent application No. 61/879,550 filed Sep. 18, 2013; the disclosure of medical infusion devices and methods of use from each is herein incorporated by reference in its entirety.

FIELD OF THE INVENTION

The invention relates generally to medical devices that infuse medical samples into implanted ports connected to the cardiovascular system of patients and more specifically to a medical infusion device having a chamber that volumetrically expands to withdraw and secure a needle after infusion.

BACKGROUND

Infusion devices that incorporate non-coring needles, such as Huber needles, are commonly used in hospitals and medical care facilities to administer chemotherapy, provide intravenous fluids and transfuse blood. Typically these devices are used to administer treatments through a medical port implanted under the skin and connected to a catheter. Accessing the medical port involves inserting the non-coring needle into a septum at the top of the port. The septum is capable of resealing after removal of the non-coring needle, thereby allowing multiple uses of a same port.

While these devices provide a reliable approach to administering treatment to the patient, their use is also associated with considerable risk to the patient and medical professional, most notably the risk of needle stick injuries and the risk of contamination by bloodborne pathogens and exposure to hazardous drugs. Needle stick injuries most commonly occur during the manual removal of the needle from the port. Typically two hands are required to remove the needle, in particular one hand to steady the port in the patient while the other hand forcibly pulls the needle from the port. As the removal of the needle requires some force, at the point the needle becomes free from the skin the sudden release of pressure can cause the needle to rebound—a phenomenon known as 'bounce-back'. During this process the hand the health care professional uses to steady the port is at risk of a needle-stick injury. Needle stick injuries carry with them the risk of contamination by bloodborne pathogens transferred from the patient to the health care professional.

Additionally, such infusion devices are often used to administer toxic substances such as those used for chemotherapy and the like. These substances are designed to kill the cancer cells in the patient however as their effects are not specific to cancerous cells, accidental exposure can put the health care professional at risk. Accidental exposure can occur either as a result of a needle stick injury with a device used to infuse the chemotherapy and/or by leaks or spillage from the needle that can occur after its removal.

Therefore there remains a need for a medical infusion device that prevents or reduces needle stick injuries and that prevents or reduces exposure to infusion media by leaks or spillage once the needle is withdrawn from the patient.

SUMMARY

In light of the risks to both health care professionals and the patients associated with the use of medical infusion devices, the present invention provides a medical infusion device in a form that prevents or reduces a likelihood of needle stick injuries, exposure to bloodborne pathogens and exposure to infusion samples.

To this end, in a first aspect of the invention a medical infusion device is provided including a chamber characterized by an upper body joined to a lower body by a reversibly collapsible sidewall, and affixed to the upper body is a downward extending needle. The upper body has two channels. The first channel is fluidly coupled to the lumen of the needle, and the second channel is fluidly coupled to the interior of the chamber. Each channel is configured for connection to tubing outside of the chamber. The lower body has a pierceable barrier that can be pierced by the needle. The chamber has a collapsed state and an expanded state, the collapsed state characterized as the sidewall being collapsed and the needle piercing entirely through the pierceable barrier, the expanded state characterized as the needle less than entirely piercing through the pierceable barrier and the chamber expanded for retaining a fluid.

The chamber can be configured to volumetrically collapse and expand using a variety of approaches, such as by providing the sidewall in a bellows-like configuration, characterized as having two or more generally linear segments joined by alternating folds at predetermined fold lines. Alternatively, the chamber sidewall can be formed from a foldable, bendable or crumpling polymer without predetermined fold lines. The chamber can include a hydrophobic filter configured to permit outgassing of the chamber.

During infusion of a sample the chamber is provided in its collapsed configuration. Volumetric expansion of the chamber retracts the needle at least partially into the chamber. Expansion occurs by introducing a fluid, such as a liquid, into the chamber to volumetrically expand the chamber. Volumetric expansion lifts the needle through its attachment at the upper body. The infusion device can include a visual indicator, such as a coloring or colored dye powder or concentrate, housed in the chamber, which when suspended in solution visually indicates the presence of fluid.

In some embodiments, the infusion device includes at least one valve, which may be integrated within the upper body or external and remote from the upper body. In some embodiments the valve only regulates flow of fluid into the first channel and thus through the needle for delivery of an infusion sample into an implanted port of a patient. In other embodiments the valve only regulates flow of fluid into the second channel and thus the chamber interior for volumetric expansion. In still other embodiments, the valve selectively directs flow to either the first or second channel and thus between the needle and chamber interior. In yet another embodiment flow is directed into the chamber and permitted to backwash the needle, the first channel, and connected tubing.

In some embodiments, the upper body and lower body have complementary locking structures to reversibly lock one another, thereby even further ensuring the chamber remains in its collapsed state during infusion and selectively permitting volumetric expansion of the chamber after infusion. The complementary locking structures can be twist locks, screw and thread or friction fit engaging surfaces.

The pierceable barrier permits fluid tight piercing and fluid tight withdrawal of the needle into the chamber. That is, in some embodiments the pierceable barrier is self-sealing or remains sealed after withdrawing a needle from the port, across the barrier and into the chamber. In some embodiments the bevel or tip remains in the piercable barrier for disposal. In other embodiments the bevel or tip of the needle is fully captured into the chamber such that fluid that fills the chamber can access the inner lumen of the needle for backflushing.

In some embodiments, the chamber deploys a blocking structure to block the needle from piercing entirely through the piercable barrier during or after expansion of the chamber. The blocking structure can be formed as sheet of nonpierceable material, such as metal or metal alloy. The blocking structure can be in the form of a jam lock that wedges against the needle to prevent piercing entirely through the barrier.

In some embodiments, the infusion device includes a mounting base for reversibly mounting the lower body. In such embodiments, the lower body is preferably configured such that the base reversibly accepts the lower body thereby permitting removal of the chamber from the mounting base after expansion of the chamber. That is, the pierceable barrier can form part of the lower body; and the lower body can be quickly and safely removed from the mounting base. The base and lower body can be friction fit into a through-bore or counterbore in the mounting base or may reversibly interlock through appropriate interlocking structures. In other embodiments, the mounting base is incorporated into the lower body as single unit that does not release the chamber.

In embodiments that include a cap that fits over the upper body, the cap and base can have complementary locking structures for further ensuring the chamber remains in its collapsed state during infusion.

In some embodiments, the lower body comprises a rigid sheath extending upward into the chamber and configured to guide the needle during expansion and sheathe the needle in the expanded state. In the collapsed state, the sheath is preferably nested within a recess in the upper body of the chamber and may be friction fit. The sheath may include an access port to improve access to the lumen of the needle when the chamber is expanded for backflushing.

In some embodiments an external mechanical guide is positioned outside of the collapsible sidewall, preferably having an end of travel release that upwardly guides the upper body from the base during expansion and releases the chamber with needle after expansion.

In related aspect, a method of delivering medication into an implanted medical port is provided, which includes: providing the infusion device in the collapsed state; piercing the implanted medical port with the needle; infusing medication into the medical port through the needle via the first channel; and introducing fluid into the chamber via the second channel thereby volumetrically expanding the chamber to withdraw the needle from the medical port to receive the tip or bevel within the pierceable barrier or the interior of the chamber. In some embodiments, the further introduction of fluid into the chamber continues to backflush the needle, optionally the first channel and optionally tubing connected to the first channel.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the invention can be better understood with reference to the following drawings, which are part of the specification and represent preferred embodiments. The components in the drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention. And, in the drawings, like reference numerals designate corresponding parts throughout the several views.

FIGS. **1**A-D depict an overview of an exemplary technical approach to medical infusion using a device according to the invention.

FIGS. **2**A-F depict an infusion device showing an exemplary mechanism for a twist lock for use in a collapsed configuration and protectively capturing the tip of the needle within the pierceable barrier when in an expanded state.

FIGS. **3**A-D depict an infusion device showing an exemplary valve mechanism to selectively deliver fluid into different channels of the device from a same exterior tubing.

FIGS. **4**A-D depict an infusion device showing an exemplary valve mechanism to selectively deliver fluid into different channels of the device from different tubing.

FIGS. **5**A-F depict an infusion device showing an exemplary volumetric expansion of a chamber having a sidewall in a bellows configuration and use of a friction fit locking mechanism.

FIGS. **6**A-J depict an infusion device showing exemplary volumetric expansion of a chamber having a bellows configuration that overcomes friction fit attachment of the upper body, lower body and base together with needle sheathing and needle capture approaches.

FIGS. **7**A-B depict an infusion device with an exemplary blocking structure preventing the needle from piercing entirely through the pierceable barrier.

FIGS. **8**A-B depict an infusion device with an exemplary external mechanical guide that upwardly guides the upper body from the base during expansion of the chamber and preferably releases the chamber after the end of travel.

FIGS. **9**A-B depict an infusion device showing an exemplary valve positioned remote from the upper body of the device.

DETAILED DESCRIPTION

The object of the invention is to provide medical infusion devices and related methods that eliminate or reduce the risk of needle stick injuries, contamination by bloodborne pathogens, exposure to hazardous fluids and other risks associated with the use of needles in conventional infusion-based methods. The above is achieved at least in part by providing a medical infusion device that removes an infusion needle from an implanted medical port using a steady or controlled fluidic force, preferably a hydraulic force, thereby reducing bounce-back injury. In addition, the medical infusion device protectively secures a withdrawn needle to avoid further risks of needle stick injury, exposure to contents of the infused sample, and exposure to patient's biological tissue or fluid. Still further, the invention provides a mechanism for backflushing the device to remove residual infusion medication or sample thereby permitting disposal of the device according to non-hazardous standards. Still further, the medical infusion device provides closed systems consistent with medically accepted safety standards. To this end, use of the invention will reduce multiple hazards associated with infusion-based medical treatments and reduce the cost of disposal.

The skilled artisan will appreciate that the infusion devices and accompanying methods can be used in a variety of medical treatments where infusion of a fluid is needed.

Among these include medical treatment where the infusion sample is a hazardous fluid or biohazardous fluid, such as a toxin, suspected toxin, whole blood or components of whole blood. Hematology and oncology patients frequently require regular infusions and therefore are nonlimiting intended patients for the device and methods. The skilled artisan will also appreciate that the medical infusion devices and methods may be connected to a variety of pumps, gravity-based drip systems, syringes and other devices that can apply a compressed or hydraulic force to administer fluids to the infusion device.

For clarity of disclosure, and not by way of limitation, the invention is discussed according to different detailed embodiments; however, the skilled artisan would recognize that features of one embodiment can be combined with other embodiments and is therefore within the intended scope of the invention.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as is commonly understood by one of ordinary skill in the art to which this invention belongs. If a definition set forth in this document is contrary to or otherwise inconsistent with a well accepted definition set forth in the art, the definition set forth in this document prevails over a contradictory definition.

The term "medical port" or "implanted port" as used herein refers to medical device that is installed beneath the skin of a patient and connected to a catheter, which fluidly connects the port to the circulatory system of the patient, typically a vein. A medical port is conventionally accessed by piercing a septum with a non-coring needle, typically referred to as a Huber needle, to access the port's interior chamber, which is coupled to a catheter for delivery into the patient's circulatory system.

The term "infusion" as used herein refers to the transfer of a fluid, such as medication or nutrients, into a patient's circulatory system. The term "infusion" is also intended to include "transfusions", such as transfusion of whole blood or components of whole blood, including but not limited to red blood cells, while blood cells, plasma, clotting factors, and platelets.

The term "fluid" as used herein refers to a substance that continually deforms under an applied shear stress. A "fluid" can be liquid or gas but is preferably liquid. Medications are typically in liquid form when infused into the patient's circulatory system through the device. Volumetric expansion of the chamber can use gas as the fluid but preferably uses liquid.

The term "fluidly coupled" or "fluidly connected" as used herein refers to the joining of two structures, each having a lumen through which a fluid may pass. A variety of complementary structures are known in the art for fluid coupling. Among these include luer locks, syringe adapters, and complementary mating structures having a central lumen.

The term "pierceable barrier" as used herein refers to a surface that may be pierced by a needle and is preferably a self-sealing septum.

The term "self-sealing" as used herein refers to the ability of the barrier to form a fluid or liquid tight seal upon withdrawal of a needle. Self-sealing materials are commonly used in the construction of septums for repeated piercing by needles and are incorporated herein by reference.

The term "blocking structure" as used herein refers to a structure that prevents a needle from entirely traversing the pierceable barrier. The "blocking structure" can be a "non-pierceable blocking structure", which as used herein refers to a structure positioned between the tip of the needle and the pierceable barrier, the structure formed from a material, such as metal or metal alloy, which can not be pierced by a needle having a gauge consistent with infusion of medication into a human. Other suitable blocking structures include a jam lock that wedges against the needle when the chamber is in an expanded state to prevent passage of the needle entirely through the barrier.

The term "closed system" as used herein refers to a medical device that mechanically prohibits the transfer of environmental contaminants into the system and escape of hazardous drug or vapor concentrations outside the system. A "closed system" is leakproof and airtight.

Reference will now be made in detail to non-limiting embodiments of the present invention by way of reference to the accompanying drawings, wherein like reference numerals refer to like parts, components, and structures.

Turning to the drawings, FIGS. **1**A-D provide an overview of a technical approach used by the invention to infuse medication into a patient and to reduce risk of injury and adverse exposure by both patient and medical professional while conducting the medical procedure. Collectively, FIGS. **1**A-D depict a medical infusion device **100**, which includes a chamber **120** having an upper end **122**, a lower end **124** and a sidewall **126**, characterized in that the chamber **120** has a collapsed state (FIG. **1**A) and an expanded state (FIG. **1**C). As shown in FIG. **1**A, the collapsed state is further characterized as having a needle **128**, preferably a non-coring or Huber needle, passing through a mounting base **130** and capable of accessing a patient's implanted medical port **132**. When in the collapsed state, fluid connection between a remote pumping source, such as a syringe or infusion pump, and the needle **128** is accomplished in part through a first channel **134** within an upper body **136**, which itself is positioned at the upper end **122** of the chamber **120**. In particular, the first channel **134** of the upper body **136** acts as a conduit to fluidly connect the needle **128** to tubing **138**, which itself connects to the remote pumping source, such as the syringe or infusion pump for supplying the infusion medication or infusion sample. The needle **128** is affixed to the upper body **136** such that upward movement of the upper body **136** upwardly moves the needle **128**. A fluid, such as a liquid medication, can pass through the first channel **134**, through the needle **128** and into the patient's implanted medical port, and thus circulatory system. In contrast, FIG. **1**C depicts a volumetrically expanded state, characterized as having the chamber **120** fluidly coupled to the needle **128**. That is, fluid (liquid or gas) retained within the chamber **120** during expansion can access the lumen of the needle **128** through the bevel/aperture **128***a*. In this state, the bevel **128***a* of the needle **128** can be housed within the chamber **120** thereby preventing or reducing exposure between the needle **128** and the patient or medical professional after the infusion procedure. Also in this state, the needle **128**, first channel **134**, and tubing **138** are ready for washing. Washing is accomplished by backflushing the needle **128**, first channel **134** and connected tubing **138** by continuing to add fluid to the expanded chamber, thereby removing residual infusion medication or sample from the device **100**, which decreases the cost of disposal since the contents are no longer hazardous. For completeness, FIG. **1**B depicts the device **100** transitioning from the collapsed state of FIG. **1**A to the volumetrically expanded state of FIG. **1**C by filling the chamber **120** with a fluid through a second channel **140** within the upper body **136**.

Turning back to FIG. **1**A, the infusion device **100**, like the other embodiments herein, can be initially provided in the expanded state, but it is preferably initially provided in the collapsed state. If provided in the expanded state a through passage having a hydrophobic filter, preferably at the upper body **136**, can be provided to permit outgassing of the chamber **120** while collapsing the chamber **120**. The devices **100** can be supplied using sterile packaging methods known in the infusion arts, such as providing a plurality of sterile, individual devices **100** with the needles **128** covered by protective covers and sealed in tear-away or peel-away packaging to ensure sterility and safety. Tubing **38**, such as polymer medical tubing connected at its proximal end to an infusion pump or syringe, can be fluidly coupled at its distal end to the first channel **134** or second channel **140** through any suitable connecting structure that permits passage of a fluid, such as couplings, conduits, adapters, connectors, barbed connectors, luer locks or other suitable connecting structures. Connection can be accomplished using snap fit connection, friction fit connection, male to female connection, tongue and groove connection or other approaches known in the medical device arts for fluidly connecting structures for the passage of fluid, and in particular liquid medication.

Also shown in FIG. **1**A, the collapsed state is further characterized as having the upper body **136** in close proximity to a base **130** due to the minimal volume within the chamber **120**, which can be accomplished by providing a chamber sidewall **126** that is folded, bent, crumpled or collapsed. In some embodiments, the chamber **120** can include a sidewall **126** that is formed from a bendable material that permits the bending or folding of the sidewall **126** at varying regions along its height without following a predetermined path or fold line thereby permitting the volume within the chamber **120** to be reduced by bending, folding or crumpling the sidewall **126**. In other embodiments, the chamber **120** includes a bellows configuration or a more ordered folding by following predetermined fold lines.

Turning to FIG. **1**B, expanding the chamber **120** involves introducing fluid into the chamber **120** thereby upwardly extending the sidewall **126** and pulling the needle **128** from the medical port **132** and into the chamber **120** for protection against needle stick injury, exposure to bloodborne pathogens, an infusion sample, or other hazardous fluids. The chamber **120** can be further guided upward through the addition of an external mechanical guide positioned outside of the collapsible sidewall **126**, preferably having an end of travel release, that upwardly guides the upper body **136** from the base **130** during expansion thereby further reducing wobble of the upper body **136** and thus needle **128** during expansion of the chamber **120**. The external mechanical guide can be joined at the lower end to the base **130** and at the upper end to the upper body **136** or the cap **142**. Upon expansion of the chamber **120** the mechanical guide preferably releases the upper body **136** from the base **130** permitting removal of the chamber **120**. Introduction can be by any suitable liquid pump or can be by pressurizing or releasing compressed gas, such compressed air. Preferably, while the sidewall **126** is capable of upward extension it is preferably inelastic and preferably does not stretch. This more effectively applies hydraulic force to remove the needle **128** from the medical port **132** during volumetric expansion of the chamber **120**. As such, when configured as a cylinder preferably the sidewall **126** does not significantly bulge radially outward when fully extended. Examples of such materials are well known in the polymer arts such as various polypropylenes, polyethylenes or other flexible polymers. While the sidewall **126** is preferably inelastic, it could be elastic as long as the modulus of elasticity results in upward extension of the upper body **134** in the expanded or deployed state.

Returning to FIG. **1**A, preferably the chamber **120** remains in its collapsed state before and during infusion of medication, such as infusion of a pharmaceutical. To this end, a variety of structures have been developed to ensure the chamber **120** remains in its collapsed state as added assurance. In some configurations the sidewall **126** is covered for further protection. In one approach, a removable cap **142** is mounted over the upper body **136** and attached to an outer surface of the base **130**, such as by complementary threads in a screw cap, tongue and groove, twist lock configuration, or friction fit. Naturally, the cap **142** can be knurled or textured to facilitate its release or removal from the base **130**, such as after infusing medication but before introducing fluid into the chamber **120** for expansion. In another embodiment, the chamber **120** is encouraged to remain in its collapsed state by adding a memory metal or a spiral-like wire structure to the chamber sidewall **126**, such as outside of or embedded within the sidewall **126**, which requires additional force to upwardly expand the chamber **120**. In still other embodiments, magnetic attraction between magnets of opposing poles can ensure the chamber **120** maintains its collapsed state and depolarization of one or more magnets, such as through modulation of an electric current, facilitates its magnetic release.

In embodiments that include a mounting base **130**, such as the embodiment depicted in FIGS. **1**A-D, the infusion device **100** includes a lower body **144** joined to the lower end **124** of the sidewall **126** of the chamber **120**. In such configurations, the lower body **144** includes a pierceable barrier **146** that retains a fluid tight seal whether or not the barrier **146** is pierced by the needle **128**. Preferably the needle is a non-coring needle **128**. Such materials are well known in the art including various rubbers, polymers or silicon used as self-sealing septums in the manufacturing of vascular access medical ports **132**. In addition, the lower body **144** can be configured to reversibly engage the base **130**, such as by twist lock, tongue and groove, snap lock or the other suitable engagement approaches; however, friction fit is most preferred. For instance, the lower body **144** can be friction fit along a circumference or perimeter of a throughbore **148** or a counterbore in the base **130**. Therefore, the throughbore **148** or counterbore can permit both snug engagement of the base **130** with the lower body **144** and provide a passage through which a needle **128** may traverse the base **130** when the lower body **144** and base **130** are engaged and the chamber **120** is in its collapsed state.

The device **100** itself can be formed from materials and manufacturing methods well known to those in the medical device field. For instance, the upper body **136**, lower body **144**, and base **130** may be formed using conventional injection molding techniques with suitable polymers used in the formation of many medical devices, such as polypropylenes. Similarly, the sidewall **126** of the chamber **120** may be formed from a rubber or bendable polymer then melted, adhered or fused to the upper **136** and lower **144** bodies. The pierceable barrier **146** may be formed from resealable silicone rubber. The lower body **144** may be provided with an aperture that is covered or filled with polymer or silicon to form the pierceable barrier **146**. Alternatively, the lower body **144** may itself be formed, at least in part, from a pierceable material, such as a self-sealing polymer to form the pierceable barrier **146**.

In view of the above and referring collectively to FIGS. **1**A-D, a method of delivering medication into or through an implanted medical port **132** is also provided, which includes providing the infusion device **100** in a collapsed configuration, aligning the needle **128** with an implanted infusion port **132**, and pressing the infusion device **100** such that needle **128** pierces the patient's skin **150** (shown generally in FIG. **1**A), then into the septum of the implanted port **132**. To further assist with insertion or handling, the uppermost portion of the upper body **136**, or an uppermost portion of a cap **142**, or a portion of the base **130** may be flattened, convex, concave, flanged, or suitably shaped to accept a hand or finger to assist in securely gripping or pressing the infusion device. Once the needle pierces the skin **150** and is inserted into the patient's infusion port **132**, the base **130** can be adhesively mounted to the patient through the use of adhesive mounts **152** positioned along the underside of the base **130** or by applying tape over outward extending flanges **154** of the base **130**. Infusion of a medical sample is accomplished by delivering the sample into the first channel **134**, which is fluidly coupled to the needle **128**, and thus the interior cavity of implanted infusion port **132**.

After infusion is complete, the device **100** can be prepared for transitioning from a collapsed state to an expanded state thereby removing the needle **128** from the medical port **132** and safely securing the needle **128**. The skilled artisan will appreciate that steps in preparing to remove the needle **128** may be performed consistent with the particular approach used for further retaining the infusion device **100** in its collapsed configuration. For instance, in some embodiments a cap **142** is removed to release the upper body **136** from the base **130**. However, in some embodiments, such as those where the cap **142** is friction fit, the cap **142** can be removed from the base **130** by delivering sufficient fluid volume into the chamber **120**.

Exemplary removal of the needle **128** from the medical port **132** and/or patient is demonstrated operationally in FIG. **1**B, which involves introducing a fluid to volumetrically expand chamber **120** via the second channel **140** to initiate chamber **120** filling and thus upward extension of the chamber sidewall **126**. The skilled artisan will appreciate that the fluid may be any suitable fluid such as water, saline, phosphate buffered saline, wash solution, bleach solution or other liquids. Alternatively, compressed gas, such as compressed air, can be applied to the chamber **120**. Preferably, fluid is continually introduced at least until the needle **128** is withdrawn from the patient, and preferably until the bevel or tip is completely housed within the chamber **120** thereby surrounding and capturing the needle **128** to avoid injury. Although the sidewall **126** is preferably extendable, it is also preferably inelastic or substantially inelastic such that the sidewall **126** or chamber **120** does not elastically stretch under filling pressure such that the upper body **134** can pull the needle **128** upwards. The sidewall **126** when expanded is preferably cylindrical as shown in FIG. **1**C but could be arc-shaped, partially spherical or any other suitable shape.

In a preferred embodiment, fluid is continually introduced into the chamber **120** after the needle **128** is completely housed within the chamber **120** such that the introduced fluid is volumetrically displaced to backwash the lumen of the **128***a* of needle **128**. The skilled artisan will appreciate that still further introduction of fluid into the chamber **120** via the second channel **140** will continue to push or backwash the lumen **128***a* of the needle **128**, the first channel **134** and any connected tubing **138** or connectors unless obstructed. In some embodiments, a visual indicator is stored in the chamber **120**, such as a colored dye or visually detectable compound, which can be provided as a powder or concentrate and that colors the backflushing solution to

visually monitor progress of backflushing. In some embodiments a portion of the chamber **120** interior is spray coated with a dye that can be dissolved in the backflushing solution for coloring. By visually monitoring backflushing, the user is notified when any potentially hazardous medication or sample is removed from the device **100** for disposal. Once backflusing is complete any tubes connected to the device can be clamped or removed. Thus, continuing to backwash the first channel **134** and tubing **138** may provide a further safety feature by preventing exposure during detachment of the device **100** from an infusion pump or syringe and allows disposal without classification as a chemical or biohazard.

As show in FIG. **1**D, the lower body **144** can be disengaged from the base **130** after filling the chamber **120** and capturing the needle **128** without risk of needle stick, exposure to the infused medication or the fluid within the chamber as the pierceable barrier **146** of the lower body **144** maintains a fluid tight seal. That is, the pierceable barrier sufficiently seals the chamber **120** to prevent leaking thereby providing a closed system once the tubes **138** are clamped, a valve integrated into the upper body **142** is closed, or a remote valve positioned away from the upper body **136** is closed. As further protection the chamber **120** may also include a blocking structure configured to block access through the piercable barrier **146** by the needle **128**. The base **130** can then be removed from the patient and the infusion device **100** safely disposed.

In a related embodiment shown in FIGS. **2**A-F, a medical infusion device **200** is provided, which includes a chamber **220** having an upper body **236**, a sidewall **226**, and a lower body **244**, characterized in that the chamber **220** has a collapsed state (FIGS. **2**C and **2**E shown without sidewall **226** for simplification) and an expanded state (FIG. **2**D). The skilled artisan would appreciate that the lower body **244** could be divided into a mounting base with lower body insert more akin to FIG. **1** if desired. As shown in FIG. **2**C, the collapsed state is further characterized as having a needle **228**, preferably a non-coring or Huber needle affixed to the upper body **236**, passing through the pierceable barrier **246** of the lower body **244** and thus being capable of accessing a patient's implanted medical port. Fluid connection between a remote source, including but not limited to a syringe, infusion pump, and a drip bag, and the needle **228** is accomplished in part through a first channel **234** within an upper body **236**, which itself is positioned at the upper end of the chamber **220** (FIG. **2**A). In particular, the first channel **234** of the upper body **236** is fluidly connected to the needle **228** and can be fluidly coupled to tubing **238**, which itself connects to a remote pumping source such as the syringe or infusion pump. Accordingly, a liquid medication can pass through the first channel **234**, through the needle **228** and into the patient. In contrast, FIG. **2**D depicts a volumetrically expanded state (also referred to as a deployed state), characterized as having the bevel of the needle **228** at or above the bottom most plane of the lower body **244** and fluid retained in the chamber **220**. For completeness, FIG. **2**A depicts the medical device **200** transitioning from the collapsed state of FIG. **2**C to the expanded state of FIG. **2**D by filling the chamber **220** with a fluid through a second channel **240** within the upper body **236**. The chamber **220** can be further guided upward through the addition of an external mechanical guide positioned outside of the collapsible sidewall **226**, that upwardly guides the upper body **236** from the lower body **244** during expansion thereby further reducing wobble of the upper body **236** and thus needle **228** during expansion of the chamber **220**. The external mechanical guide can be joined at the lower end to the lower body **244** and at the upper end to the upper body **236**.

The device **200** can be formed from materials and manufacturing methods known to those in the medical device field. For instance, the upper body **236** and lower body **244** may be formed using conventional injection molding techniques with suitable polymers used in the formation of many medical devices such as polypropylene and other polymers used in the construction of medical devices. Similarly, the sidewall **226** of the chamber **220** may be formed from rubber or foldable polymer then adhered or fused to the upper body **236** and lower body **244**. The pierceable barrier **246** may be formed from self-sealing silicone rubber. The lower body **244** may be provided with an aperture that is covered or filled with polymer or silicone to form the pierceable barrier **246**. Alternatively, the lower body **244** may itself be formed, at least in part, from a pierceable material, such as a self-sealing polymer to form the pierceable barrier **246**.

This embodiment exemplifies features that may be incorporated into other embodiments, namely, the upper body **236** and lower body **244** have complementary interlocking structures **256***a*, **256***b*, such as a twist-lock or interlocking bayonet and catch, where the upper body **236** and lower body **244** interlock to further ensure that the chamber **220** (the sidewall **226** removed for simplicity of viewing in FIGS. **2**B, C, E, F) remains in a collapsed state during infusion. In addition, as depicted in FIGS. **2**B-F, the pierceable barrier **246** may be configured to protectively hold the needle **228** when in the device is in the expanded state.

Accordingly, use of the device shown in FIGS. **2**A-F can provide a method of delivering medication into or through an implanted medical port, which includes providing the infusion device **200** in a collapsed configuration, aligning the needle **228** with an implanted infusion port, and pressing the infusion device **200** such that needle **228** pierces the patient's skin, then into the septum of the implanted port. To further assist with insertion or handling, the uppermost portion of the upper body **236**, or a portion of the lower body **244** may be flattened, convex, concave, flanged, curved or suitably shaped to accept a hand or finger to assist in securely gripping or pressing the infusion device **200**. Once the needle **228** pierces the skin and is inserted into the patient's infusion port, the lower body **244** can be adhesively mounted to the patient through the use of adhesive mounts positioned along the underside of the lower body **244** or by applying tape over outward extending flanges of the lower body **244**. Infusion of a medical sample is accomplished by delivering the sample into the first channel **234**, which is fluidly coupled to the needle **228**, and thus implanted infusion port.

After infusion is complete, the upper body **236** is rotated in relation to the lower body **244** such that the interlocking structures **256***a*, **256***b* are released. A fluid is introduced into the expandable chamber **220** via the second channel **240** to initiate volumetric chamber **220** filling and upward extension of the chamber sidewall **226**. The skilled artisan will appreciate that the fluid may be any suitable fluid such as water, saline, phosphate buffered saline, wash solution, bleach solution or other liquids. Alternatively, compressed gas, such as compressed air, can be applied to the chamber **220**. Preferably, fluid is continually introduced at least until the needle **228** is withdrawn from the port, and until the bevel or tip of the needle **228** is at or above the lowermost plane of the lower body **244**. In the expanded or deployed state the needle **228** may remain captured within the pierceable barrier **246**, which acts to seal the bottom of the chamber **220** and retain the fluid. The device **200** is then removed from the patient. In other embodiments, the needle **228** is entirely withdrawn into the chamber **220** to permit backflushing of the needle **228**, channel **234** and optionally connected tubing **238**. As with the embodiment above, a visual indicator may be employed to monitor backflushing to ensure removal of potentially hazardous medication or solution and therefore may notify the user when the device **200** may be disposed of without special designation as a hazardous material. Further protection against needle stick can be accomplished by providing a blocking structure or a nonpierceable blocking structure configured to block access through the pierceable barrier **246** by the needle **228** upon expansion.

In another related embodiment shown in FIGS. **3**A-D, a medical infusion device **300**, is provided, which includes a chamber **320** having an upper body **336**, a sidewall **326**, and a lower body **344**, characterized in that the chamber **320** has a collapsed state (FIG. **3**B with sidewall **326** removed for simplicity for viewing) and an expanded state (FIG. **3**D). The skilled artisan would appreciate that the lower body **344** could be divided into a mounting base with lower body insert more akin to FIG. **1** if desired. As shown in FIG. **3**B, the collapsed state is further characterized as having a needle **328**, preferably a non-coring or Huber needle affixed to the upper body **336**, passing through the lower body **244** and thus being capable of accessing a patient's implanted medical port. Fluid connection between a remote source, including but not limited to a syringe or infusion pump, with the needle **328** is accomplished in part through a valve **358**, which forms part of the upper body **336** and selectively accesses either the needle **328** or a passage **340** to the inner chamber **320**. In particular, the valve **358** selectively connects a same tubing **338** to either the needle **328** or the inner chamber **320** at one end and a remote pumping source such as one or more syringes or infusion pumps at the other end through one or more suitable connectors, in particular one or more y-connectors or remote valves positioned away from the upper body **336**. Accordingly, a liquid medication can pass through the valve **358**, through the needle **328** and into the patient. In contrast, FIG. **3**D depicts an expanded or deployed state, characterized as having the tip of the needle **328** at or above the bottom most plane of the lower body **344** such that the medical profession is protected from needle stick. For completeness, FIG. **3**A depicts the medical device **300** transitioning from the collapsed state of FIG. **3**B to the expanded state of FIG. **3**D by selecting the valve **358** to access the inner chamber **320** and filling the chamber **320** with a fluid. The chamber **320** can be further guided upward through the addition of an external mechanical guide positioned outside of the collapsible sidewall **326** that upwardly guides the upper body **336** from lower body **344** during expansion thereby further reducing wobble of the upper body **336** and thus needle **328** during expansion of the chamber **320**. The external mechanical guide can be joined at the lower end to the lower body **344** and at the upper end to the upper body **336**.

The device **300** can be formed from materials and manufacturing methods known to those in the medical device field. For instance, the upper body **336** and lower body **344** may be formed using conventional injection molding techniques with suitable polymers used in the formation of many medical devices such as polypropylenes of other suitable polymers. Similarly, the sidewall **326** of the chamber **320** may be formed from rubber or foldable polymer then adhered or fused to the upper body **336** and lower body **344**. The pierceable barrier **346** may be formed from self-sealing silicone rubber. The lower body **344** may be provided with an aperture that is covered or filled with polymer or silicone to form the pierceable barrier **346**. Alternatively, the lower body **344** may itself be formed, at least in part, from a pierceable material, such as a self-sealing polymer or silicone to form the pierceable barrier **346**.

This embodiment exemplifies features that may also be incorporated into other embodiments, namely, a rotating valve **358** that forms part of the upper body **336** and selectively delivers fluid to either the needle **328** or the chamber **320** from a same tubing **338** thereby permitting the user to selectively deliver fluid to either the needle **328** or the chamber **320** through rotation of a handle **360**, which is typically a 180 degree rotation. Thus, operation of the infusion device **300** would typically include rotating the handle **360**. Closing the valve **358** can be accomplished by about 45 to 135 degree rotation of the handle **360** to prevent access to both channels **334**, **340**.

Accordingly, use of the device shown in FIGS. **3**A-D can provide a method of delivering medication into or through an implanted medical port, which includes providing the infusion device **300** in a collapsed configuration with the valve **358** designating fluid communication with the needle **328**, aligning the needle **328** with an implanted infusion port, and pressing the infusion device **300** such that needle **328** pierces the patient's skin, then into the septum of the implanted port. To further assist with insertion or handling, the uppermost portion of the upper body **336**, or a portion of the lower body **344** may be flattened, convex, concave, flanged, curved or suitably shaped to accept a hand or finger to assist in securely gripping or pressing the infusion device **300**. Once the needle **328** pierces the skin and is inserted into the patient's infusion port, the lower body **344** can be adhesively mounted to the patient through the use of adhesive mounts positioned along the underside of the lower body **344** or by applying tape over outward extending flanges of the lower body **344**. Infusion of a medical sample is accomplished by delivering the sample into the first channel **334**, which is fluidly coupled to the needle **328**, and thus implanted infusion port.

After infusion is complete, the upper body **336** is rotated in relation to the lower body **344** such that the interlocking structures **356***a*, **356***b* are released. The handle **360** is rotated to designate fluid connection with the inner chamber **320**. A fluid is introduced into the expandable chamber **220** via the same tubing **338** to initiate volumetric chamber **320** filling and upward extension of the chamber sidewall **326**. The skilled artisan will appreciate that the fluid may be any suitable fluid such as water, saline, phosphate buffered saline, wash solution, bleach solution or other liquids. Alternatively, compressed gas, such as compressed air, can be applied to the chamber **320**. Preferably, fluid is continually introduced at least until the needle **328** is withdrawn from the port, and until the bevel or tip of the needle **328** is at or above the lowermost plane of the lower body **344**. In the expanded or deployed state the needle **328** may remain captured within the pierceable barrier **346**, which acts to seal the bottom of the chamber **320**. Alternatively, the bevel or tip of the needle **328** may be captured entirely within the chamber **320** and away from the piercable barrier **346**. The device **300** is then removed from the patient. The chamber **320** is therefore a closed system defined by the piercable barrier **346** and selection of the valve **358** in a closed state. Further protection against needle stick can be accomplished by providing a blocking structure configured to block access entirely through the piercable barrier **346** by the needle **328** upon expansion.

In another related embodiment shown in FIGS. **4**A-D, a medical infusion device **400**, is provided, which includes a chamber **420** having an upper body **436**, a sidewall **426**, and a lower body **444**, characterized in that the chamber **420** has a collapsed state (FIG. **4**B with sidewall **426** removed for viewing simplicity) and an expanded state (FIGS. **4**C, **4**D). The skilled artisan would appreciate that the lower body **444** could be divided into a mounting base with lower body insert more akin to FIG. **1** if desired. As shown in FIG. **4**B, the collapsed state is further characterized as having a needle **428**, preferably a non-coring or Huber needle affixed to the upper body **436**, passing through the lower body **444** and thus being capable of accessing a patient's implanted medical port. Fluid connection between a remote source, including but not limited to a syringe or infusion pump, and the needle **428** is accomplished in part through an integrated valve **458** that selectively prevents or permits access to a first channel **434** within an upper body **436**, which itself is positioned at the upper end of the chamber **420**. In particular, the first channel **434** of the upper body **436** is fluidly connected to the needle **428** and can be fluidly coupled to tubing **428** by the appropriate valve **458** position, thereby permitting infusion from a remote pumping source such as the syringe or infusion pump. Accordingly, a liquid medication can pass across the valve **458**, through the first channel **434**, through the needle **428** and into the patient. In contrast, FIGS. **4**C, **4**D depict a volumetrically expanded state (also referred to as a deployed state), characterized as having the bevel or tip of the needle **428** at or above the bottom most plane of the lower body **444**. For completeness, FIG. **4**A depicts the medical device **400** transitioning from the collapsed state of FIG. **4**B to the expanded state of FIGS. **4**C, **4**D by filling the chamber **420** with a fluid through a second channel **440** within the upper body **436**. The chamber **420** can be further guided upward through the addition of an external mechanical guide positioned outside of the collapsible sidewall **426** that upwardly guides the upper body **436** from the lower body **444** during expansion thereby further reducing wobble of the upper body **436** and thus needle **428** during expansion of the chamber **420**. The external mechanical guide can be joined at the lower end to the lower body **444** and at the upper end to the upper body **436**.

The device **400** can be formed from materials and manufacturing methods known to those in the medical device field. For instance, the upper body **436** and lower body **444** may be formed using conventional injection molding techniques with suitable polymers used in the formation of many medical devices such as polypropylenes or other polymers. Similarly, the sidewall **426** of the chamber **420** may be formed from rubber or foldable polymer then adhered or fused to the upper body **436** and lower body **444**. The pierceable barrier **446** may be formed from resealable silicone rubber. The lower body **444** may be provided with an aperture that is covered or filled with polymer or silicone to form the pierceable barrier **446**. Alternatively, the lower body **444** may itself be formed, at least in part, from a pierceable material, such as a self-sealing polymer or silicone to form the pierceable barrier **446**.

This embodiment exemplifies features that may also be incorporated into other embodiments, namely, a rotating valve **458** that forms part of the upper body **436** that selectively prevents or permits fluid delivery through the needle **428**, and interlocking structures **456***a*, **456***b* that are rubber protrusions and corresponding recesses for detachment or release by chamber **420** filling. Thus, operation of the infusion device **400** would typically include rotating the handle **460** to open or close the valve **458** and releasing the interlocking structures **456***a*, **456***b* in response to increasing fluid pressure during chamber **420** filling.

Accordingly, use of the device as shown in FIGS. **4**A-D can provide a method of delivering medication into or through an implanted medical port, which includes providing the infusion device **400** in a collapsed configuration, selecting the valve **458** to fluidly connect with the needle **428**, aligning the needle **428** with an implanted infusion port, and pressing the infusion device **400** such that the needle **428** pierces the patient's skin, then into the septum of the implanted port. To further assist with insertion or handling, the uppermost portion of the upper body **436**, or a portion of the lower body **444** may be flattened, convex, concave, flanged, curved or suitably shaped to accept a hand or finger to assist in securely gripping or pressing the infusion device **400**. Once the needle **428** pierces the skin and is inserted into the patient's infusion port, the lower body **444** can be adhesively mounted to the patient through the use of adhesive mounts positioned along the underside of the lower body **444** or by applying tape over outward extending flanges of the lower body **444**. Infusion of a medical sample is accomplished by delivering the sample through the valve **458**, through first channel **434**, which is fluidly coupled to the needle **428**, and into the implanted infusion port.

After infusion is complete, the handle **464** is rotated so that the valve **458** designates fluid connection with the inner chamber **420**. A fluid is introduced into the expandable chamber **420** to initiate volumetric chamber **420** filling and upward extension of the chamber sidewall **426**, which overcomes the holding force of the rubber protrusions. The skilled artisan will appreciate that the fluid may be any suitable fluid such as water, saline, phosphate buffered saline, wash solution, bleach solution or other liquids. Alternatively, compressed gas, such as compressed air, can be applied to the chamber **420**. Preferably, fluid is continually introduced at least until the needle **428** is withdrawn from the port, and until the bevel or tip of the needle **428** is at or above the lowermost plane of the lower body **444**. In the expanded or deployed state the needle **428** may remain captured within the piercable barrier **446**, which acts to seal the bottom of the chamber **420** and retain the fluid. Alternatively, the needle can be raised such that the bevel or tip is housed within the chamber **420**. The device **400** is then removed from the patient. Continued flow of solution into the chamber would then backflush the needle **428**, the first channel **434** and the tubing **438**. As with the embodiments above, a visual indicator may be employed to monitor backflushing to ensure removal of potentially hazardous medication or solution and therefore may notify the user when the device **400** may be disposed of without special designation as a hazardous material. Further protection against needle stick can be accomplished by providing a blocking structure configured to block access entirely through the pierceable barrier **426** by the needle **428** upon expansion.

In another related embodiment shown in FIGS. **5**A-E, a medical infusion device **500**, is provided, which includes a chamber **520** having an upper body **536**, a sidewall **526**, and a lower body **544**, characterized in that the chamber **520** has a collapsed state (FIG. **5**B) and an expanded state (FIG. **5**C). The skilled artisan would appreciate that the lower body **544** could be divided into a mounting base with lower body insert more akin to FIG. **1** if desired. As shown in FIG. **5**B, the collapsed state is further characterized as having a needle **528**, preferably a non-coring or Huber needle affixed to the upper body **536**, passing through the lower body **544** and thus being capable of accessing a patient's implanted medical port. Fluid connection between a remote source, including but not limited to a syringe or infusion pump, and the needle **528** is accomplished in part through a first channel **534** within an upper body **536**, which itself is positioned at the upper end of the chamber **520**. In particular, the first channel **534** of the upper body **536** is fluidly connected to the needle **528** and can be fluidly coupled to tubing **538** thereby permitting infusion from a remote pumping source such as the syringe or infusion pump. Accordingly, a liquid medication can pass across through the first channel **534**, through the needle **528** and into the patient. In contrast, FIG. **5**C depicts an expanded state (also referred to as a deployed state), characterized as having the bevel or tip of the needle **528** at or above the bottom most plane of the lower body **544**. Transition from a collapsed state to an expanded or deployed state occurs by filling the chamber **520** with a fluid through a second channel **540** within the upper body **536**. The chamber **520** can be further guided upward through the addition of an external mechanical guide positioned outside of the collapsible sidewall **526** that upwardly guides the upper body **536** from the lower body **544** during expansion thereby further reducing wobble of the upper body **536** and thus needle **528** during expansion of the chamber **520**. The external mechanical guide can be joined at the lower end to the lower body **544** and at the upper end to the upper body **536**.

The device **500** can be formed from materials and manufacturing methods known to those in the medical device field. For instance, the upper body **536** and lower body **544** may be formed using conventional injection molding techniques with suitable polymers used in the formation of many medical devices such as polypropylenes or other polymers. Similarly, the sidewall **526** of the chamber **520** may be formed from rubber or foldable polymer then adhered or fused to the upper body **536** and lower body **544**. The pierceable barrier **546** may be formed from resealable silicone rubber. The lower body **544** may be provided with an aperture that is covered or filled with polymer or silicone to form the pierceable barrier **546**. Alternatively, the lower body **544** may itself be formed, at least in part, from a pierceable material, such as a self-sealing polymer or silicone to form the pierceable barrier **546**.

This embodiment exemplifies features that may also be incorporated into other embodiments, namely, friction fit connectors **556***a*, **556***b* to ensure the chamber **520** remains in a collapsed state during infusion of a medical sample. Further, the chamber sidewall **526** is provided in a bellows configuration, where a series of segments **566***a*, **566***b* between alternating folds **568***a*, **568***b* are foldable in a predetermined or bellows-like configuration. In the bellows-like configuration the segments **566***a*, **566***b* between folds **568***a*, **568***b* can be rigid, flexible or bendable; however, the chamber sidewall **526** should fold at the predetermined fold lines **568***a*, **568***b*.

Accordingly, use of the device as shown in FIGS. **5**A-E can provide a method of delivering medication into or through an implanted medical port, which includes providing the infusion device **500** in a collapsed configuration, aligning the needle **528** with an implanted infusion port, and pressing the infusion device **500** such that needle **528** pierces the patient's skin, then into the septum of the implanted port. To further assist with insertion or handling, the uppermost portion of the upper body **536**, or a portion of the lower body **544** may be flattened, convex, concave, flanged, curved or suitably shaped to accept a hand or finger to assist in securely gripping or pressing the infusion device

500. Once the needle **528** pierces the skin and is inserted into the patient's infusion port, the lower body **544** can be adhesively mounted to the patient through the use of adhesive mounts positioned along the underside of the lower body **544** or by applying tape over outward extending flanges of the lower body **544**. Infusion of a medical sample is accomplished by delivering the sample through the first channel **534**, which is fluidly coupled to the needle **528**, and into the implanted infusion port.

After infusion is complete, a fluid is introduced into the expandable chamber **520** to initiate chamber **520** filling, release of friction fit connectors **556***a*, **556***b*, and upward extension of the chamber sidewall **526**. The skilled artisan will appreciate that the fluid may be any suitable fluid such as water, saline, phosphate buffered saline, wash solution, bleach solution or other liquids. Alternatively, compressed gas, such as compressed air, can be applied to the chamber **520**. Preferably, fluid is continually introduced at least until the needle **528** is withdrawn from the port, and until the bevel or tip of the needle **528** is at or above the lowermost plane of the lower body **544**. In the expanded or deployed state the needle **528** may remain captured within the pierceable barrier **546**, which acts to seal the bottom of the chamber **520**. Alternatively, the needle can be raised such that the bevel or tip is housed within the chamber **520**. The device **500** is then removed from the patient. Continued flow of solution into the chamber would then backflush the needle **528**, the first channel **534** and the tubing **538**. As with the embodiment above, a visual indicator may be employed to monitor backflushing to ensure removal of potentially hazardous medication or solution and therefore may notify the user when the device **500** may be disposed of without special designation as a hazardous material. Further protection against needle stick can be accomplished by providing a blocking structure configured to block access through the pierceable barrier **546** by the needle **528** upon expansion.

In another related embodiment shown in FIGS. **6**A-J, a medical infusion device **600**, is provided, which includes a chamber **620** having an upper body **636**, a sidewall **626**, and a lower body **644**, shown releasably friction fit to a mounting base **630**, characterized in that the chamber **620** has a collapsed state (FIGS. **6**A-F) and an expanded state (FIG. **6**G-J). The lower body **644** could be formed as a single unit with the mounting base **630** if selective release of the chamber **620** is from a base **630** is not desired. As shown in FIG. **6**D, the collapsed state is further characterized as having a needle **628**, preferably a non-coring or Huber needle affixed to the upper body **636**, passing through the lower body **644** and thus capable of accessing a patient's implanted medical port. Although the device **600** is preferably provided in the collapsed state, collapsing the device **600** can involve downwardly pushing the upper body **636** against the lower body **644**. A hydrophobic filter **676** in a through passage into the chamber **620** may allow air to escape from the chamber **620** while collapsing the chamber **620**. Fluid connection between a remote source, including but not limited to a syringe or infusion pump, and the needle **628** is accomplished in part through a first channel **634** within an upper body **636**, which itself is positioned at the upper end of the chamber **620**. In particular, the first channel **634** of the upper body **636** acts as a conduit to fluidly connect the lumen of the needle **628** to tubing **638** thereby permitting infusion from a remote pumping source such as the syringe or infusion pump through the needle **628**. Accordingly, a liquid medication can pass through the first channel **634**, through the needle **628** and into the patient's implanted port. In contrast, FIG. **6**H depicts an expanded or deployed state, characterized as having the bevel or tip of the needle **628** at or above the bottom most plane of the lower body **644** and preferably either securely held in the pierceable barrier **646** as shown in FIG. **6**J or housed within the chamber **620** as shown in FIG. **6**H. As shown in FIGS. **6**D, **6**F, **6**G, a tubular sheath **668** forms part of the lower body **644** of the chamber **620** and extends upward at least partially along the height of the chamber **620** acting as a guiding structure to further guide and retain the needle **628** in proper linear alignment during deployment of the infusion device **600** and may act to sheathe the bevel or tip of the needle **628** when entirely captured by the chamber **620** as shown in FIG. **6**H. The sheath **668** may also be provided with an access port **670** to more efficiently fluidly access a sheathed needle **628** by fluid contents of the chamber **620**. Transitioning from a collapsed state to an expanded or deployed state occurs by filling the chamber **620** with a fluid through a second channel **640** acting as a conduit through the upper body **636**. The chamber **620** can be further guided upward through the addition of an external mechanical guide positioned outside of the collapsible sidewall **626**, preferably having an end of travel release, that upwardly guides the upper body **636** from the base **630** during expansion thereby further reducing wobble of the upper body **636** and thus needle **628** during expansion of the chamber **620**. The external mechanical guide can be joined at the lower end to the base **630** and at the upper end to the upper body **636**. Upon expansion of the chamber **620**, preferably the mechanical guide releases the upper body **636** from the base **630** thereby releasing the chamber **620** with needle **628**. The device **600** can be formed from materials and manufacturing methods known to those in the medical device arts. For instance, the upper body **636**, lower body **644**, base **630** and sheath **668** may be formed using conventional injection molding techniques with suitably rigid polymers used in the formation of many medical devices, such as polypropylene or polymer. Similarly, the sidewall **626** of the chamber **620** may be formed from rubber or foldable polymer then adhered or fused to the upper body **636** and lower body **644**. The pierceable barrier **646** may be formed from resealable silicone rubber. The lower body **644** may be provided with an aperture that is covered or filled with polymer or silicone to form the pierceable barrier **446**, preferably in alignment with the sheath **668**. Alternatively, the lower body **144** may itself be formed, in part, from a pierceable material, such as a self-sealing polymer or silicone to form the pierceable barrier **146**.

This embodiment exemplifies features that may also be incorporated into the other embodiments, namely, friction fit connection about the perimeter of the upper body **636** and the base **630** when the infusion device **600** is provided in the collapsed state. In addition, by providing an recess **674** in the upper body **636** for nesting the sheath **668** as shown in FIGS. **6**D, **6**H, further friction fit connection between the upper body **636** and the lower body **644** can be provided thereby eliminating the desire for additional locking structures to securely maintain the infusion device **600** in the collapsed state. In other embodiments, the recess **674** is spaced apart from the sheath **668** to avoid friction fitting. Still further, by forming a gap **672** between the upper body **636** that is sized to contact sidewall **626** of the chamber **620** when the infusion device **600** is in a compressed state, friction fitting between the upper body **636** and sidewall **626** can be achieved thereby further securing of the upper body **636** to the lower body **644**. However, in some embodiments the gap **672** is sized to avoid contact with but instead only covers the sidewall **626**.

Accordingly, use of the device as shown in FIGS. **6**A-J can provide a method of delivering medication into or through an implanted medical port, which includes providing the infusion device **600** in a collapsed configuration, aligning the needle **628** with an implanted infusion port, and pressing the infusion device **600** such that needle **628** pierces the patient's skin, then into the septum of the implanted port. To further assist with insertion or handling, the upper body **636**, or base **630** may be flattened, convex, concave, flanged, curved or suitably shaped to accept a hand or finger to assist in securely gripping or pressing the infusion device **600**. Once the needle **628** pierces the skin and is inserted into the patient's infusion port, the base **630** is optionally adhesively mounted to the patient through the use of adhesive mounts positioned along the underside of the base **630** or by applying tape over an outward extending flange of the base **630**. Infusion of a medical sample is accomplished by delivering the sample through the first channel **634**, which is fluidly coupled to the needle **628**, and into the implanted infusion port.

After infusion is complete, fluid is introduced into the expandable chamber **620** to initiate chamber **620** filling at a sufficient force to overcome friction fit attachment between the upper body **636** and base **630** and optionally between the upper body **636**, sheath **668** and sidewall **626**, thereby unfolding the bellows and upwardly extending the chamber sidewall **626**. The skilled artisan will appreciate that the fluid may be any suitable fluid such as water, saline, phosphate buffered saline, wash solution, bleach solution or other liquids. Alternatively, compressed gas, such as compressed air, can be applied to the chamber **620**. Preferably, fluid is continually introduced at least until the needle **628** is withdrawn from the port, and until the bevel or tip of the needle **628** is at or above the lowermost plane of the lower body **644**. In the expanded or deployed state the needle **628** may remain captured within the pierceable barrier **646**, which acts to seal the bottom of the chamber **620**. Alternatively, the needle can be raised such that the bevel or tip is housed within the chamber **620** and in particular sheathed by the sheath **668**. Once the needle **628** is removed from the port, the device **600** releases. Continued flow of solution into the chamber can then pass through the access port **670** and backflush the needle **628**, the first channel **634** and the tubing **638** as desired. As with the embodiments above, a visual indicator may be employed to monitor backflushing to ensure removal of potentially hazardous medication or solution and therefore may notify the user when the device **600** may be disposed of without special designation as a hazardous waste. In addition, further protection against needle stick can be accomplished by providing a blocking structure configured to block access through the piercable barrier **646** by the needle **628** upon expansion of the chamber. Still further, the device **100** may include a remote valve along the tubing **638** to regulate flow into the needle **620** and/or into the chamber **620**.

Embodiments above can incorporate a blocking structure to prevent the needle from traversing the entirety of the pierceable barrier after expansion of the chamber thereby further ensuring against needle stick injury and exposure to infusion samples. The blocking structure can be provided in a variety of configurations. In some embodiments, it is a material that is selectively presented between the tip of the needle and pierceable barrier, where the blocking structure is formed from a material that is not pierceable by the needle. Such structures can be suitably positioned for blocking during or at chamber expansion, such as but not limited by spring action, hinged, through the use of memory metals, or release from a suspended recess for positioning by gravitational forces. Such materials may be plastics of suitable formulation or thickness, metal, metal alloy or other materials that are not pierceable using forces conventionally used during insertion of a needle into a medical port. A related approach is shown in FIGS. **7**A and **7**B where a blocking structure **780** in the form of a jam lock is upwardly suspended by the needle **728** when in the collapsed configuration (FIG. **7**A) and is configured to fall and jam or wedge against the needle **728** when in the expanded configuration (FIG. **7**B), thereby preventing passage entirely across the pierceable barrier **746**.

Embodiments above can incorporate an external mechanical guide, preferably having an end of travel release, to further assist in upwardly guiding the upper body from the base during expansion of the chamber. This configuration further reduces the likelihood of the upper body and thus needle from wobbling during expansion. An exemplary external mechanical guide **882** is depicted in FIGS. **8**A-B. Preferably there are two external mechanical guides **882** positioned at opposing sides of the device **800**. Each mechanical guide **882** is preferably formed as two rigid segments **882**A, **882**B hinged at about the center to permit folding and unfolding thereby outwardly collapsing (FIG. **8**A) and upwardly expanding (FIG. **8**B) with the chamber **820**. Preferably, the mechanical guide **882** is joined to the base **844** at one end, such as by gluing or injection molding, and is releasably joined to the upper body **836** at the opposing end, such as by a releasable hook **882**C and complementary recess on the upper body **836**. A hook **882**C and recess configuration permits an end of travel release where the hook **882**C rotates along the recess or slot until releasing when in the expanded state if desired. The mechanical guide **882** is typically formed from polymer plastic and narrowed at its center to form the hinge.

Each of the above embodiments can incorporate a valve positioned remote from the upper body for selectively connecting external sources to the chamber and/or needle. An exemplary configuration is shown in FIGS. **9**A-B, where during the collapsed configuration (FIG. **9**A), a remote valve **958** is selected to permit flow through a first line **938**A, such as by presenting the valve **958** with an upward extending body **959**; and during the expanded configuration (FIG. **9**B), the valve **958** is selected, such as by pressing the body **959** downward, to permit flow through a second line **938**B (coupled to a wash solution) to access the chamber **920** and backflush the needle and optionally first line **938**A to remove residual infusion sample.

The invention described herein may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The specific embodiments previously described are therefor to be considered as illustrative of, and not limiting, the scope of the invention.

What is claimed is:

1. A medical infusion device comprising:

a chamber characterized by an upper body joined to a lower body by a reversibly collapsible sidewall, affixed to the upper body is a downward extending needle, wherein the upper body comprises two channels that do not intersect in the upper body, further wherein a first channel is fluidly coupled to the needle and a second channel is fluidly coupled to the interior of the chamber, further wherein each channel is configured to receive a fluid from outside of the chamber, the lower body comprising a pierceable barrier that can be pierced by the needle;

wherein the chamber has a collapsed state and an expanded state, the collapsed state characterized as the sidewall being collapsed and the needle piercing entirely through the pierceable barrier, the expanded state characterized as the needle less than entirely piercing through the pierceable barrier and the chamber capable of retaining a fluid, wherein the chamber is configured to transition from the collapsed state to the expanded state by introducing fluid into the interior of the chamber through the second channel.

2. The medical infusion device according to claim **1**, wherein the needle is a non-coring needle and the pierceable barrier is a self-sealing septum, optionally formed from silicon.

3. The infusion device according to claim **1**, wherein the chamber collapses by folding the sidewall.

4. The infusion device according to claim **3**, wherein the sidewall comprises a bellows configuration formed as a plurality of segments joined by alternating folds configured to fold and unfold at predetermined fold lines.

5. The infusion device according to claim **3**, wherein the sidewall is formed from a foldable polymer without predetermined fold lines.

6. The infusion device according to claim **1**, wherein the upper body and lower body have complementary locking structures or are configured for friction fit engagement when the device is in the collapsed state.

7. The infusion device according to claim **6**, wherein the entire sidewall is captured within the upper body and lower body when locked or engaged.

8. The infusion device according to claim **1**, wherein the fluid is a liquid.

9. The infusion device according to claim **1**, further comprising a valve that selectively permits fluid transfer from outside of the device into the needle or the chamber.

10. The infusion device according to claim **9**, wherein the valve is positioned at the upper body.

11. The infusion device according to claim **9**, wherein the valve is a remote valve that is positioned remote from the upper body.

12. The infusion device according to claim **1**, further comprising a rigid sheath fixedly positioned at the lower body and extending upward into the chamber to sheathe the needle in the expanded state.

13. The infusion device according to claim **12**, wherein the sheath is nested within upper body of the chamber when the chamber is in the collapsed state.

14. The infusion device according to claim **12**, wherein the sheath is in friction fit engagement with a recess of the upper body when the chamber is in the collapsed state.

15. The infusion device according to claim **1**, wherein the upper body further comprises a hydrophobic filter in a through passage into the chamber configured to permit outgassing of the chamber.

16. The infusion device according to claim **1**, further comprising a visual indicator, optionally a dye, housed in the chamber or second channel that colors a solution added to the chamber.

17. The infusion device according to claim **1**, further comprising a mounting base that reversibly receives the lower body.

18. The infusion device according to claim **17**, wherein the upper body and base have complementary locking structures or are configured for friction fit engagement when the device is in the collapsed state.

19. The infusion device according to claim **17**, further comprising a cap that fits over the upper body, the cap and base having complementary locking structures or are configured for friction fit engagement when the device is in the collapsed state.

20. The infusion device according to claim **1**, further comprising a blocking structure positioned within the chamber and configured to block access to the pierceable barrier by needle when the chamber is in the expanded state.

21. The infusion device according to claim **1**, wherein the second channel ends at the chamber thereby preventing passage of fluid from the second channel across the piercable barrier when in the collapsed state.

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